Supreme Court, U.S.
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No. _____

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Petitioner,

v.

RHONDA M. MEDOWS, Secretary, Agency for Health Care Administration of the State of Florida, and BOB SHARPE, Deputy Secretary of Medicaid, Agency for Health Care Administration of the State of Florida,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the federal Medicaid statute, 42 U.S.C. § 1396r-8, allows a state to impose broad restrictions on Medicaid patients' access to prescription drugs if manufacturers refuse to provide greater rebates than the rebates specified in the federal statute.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

PhRMA is a not-for-profit incorporated membership organization. There are no parent corporations or publicly held companies that own 10 percent or more of PhRMA's stock. A list of PhRMA's members may be found at http://www.phrma.org/whoweare/members.

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the court of appeals (App. 1-38) is reported at 304 F.3d 1197 (11th Cir. 2002). The opinion of the district court (App. 39-59) is reported at 184 F. Supp. 2d 1186 (N.D. Fla. 2001).

JURISDICTION

The judgment of the court of appeals was entered on September 6, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. Article VI of the Constitution, providing that "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land."

2. Section 1927 of the Social Security Act ("SSA"), 42 U.S.C. § 1396r-8, governing Medicaid coverage of prescription drugs. (App. 60-74.)

3. Laws of Florida, ch. 2001-104, amending, *inter alia*, Fla. Stat. §§ 409.91195, 409.912, creating Florida's "preferred drug formulary" and supplemental rebate requirement. (App. 75-88.)

INTRODUCTION

This case, like *PhRMA v. Concannon* (No. 01-188), involves a state's attempt to restrict Medicaid patients' access to prescription drugs as a means of obtaining rebates from drug manufacturers beyond the rebates specified in the federal Medicaid statute. In *Concannon*, Maine seeks to obtain additional rebates from drug manufacturers to finance a non-Medicaid prescription drug program. In this case, Florida seeks to obtain additional rebates to reduce the prescription drug costs of its Medicaid program. In both cases, the state seeks to obtain the additional rebates by threatening to impose restrictions—in the form of a "prior authorization" requirement—on Medicaid patients' access to drugs of manufacturers who refuse to provide the additional rebates.

In each case, the state is thus holding Medicaid patients hostage to the state's attempt to extract additional rebates from drug manufacturers. If a drug manufacturer complies, Medicaid patients continue to enjoy unimpeded access to the manufacturer's drugs. If a manufacturer refuses, patient access to the manufacturer's drugs is barred unless the physician obtains from the state specific advance approval ("prior authorization") to prescribe the drug. The states understand that requiring physicians to obtain prior authorization to prescribe a drug drastically reduces the drug's utilization: that is why they view the threat of prior authorization as an effective means of securing additional manufacturer rebates.

This case, like *Concannon*, merits review by this Court. Just as the First Circuit's decision in *Concannon* jeopardizes Medicaid patients by restricting their access to prescription drugs in order to promote non-Medicaid objectives, so the Eleventh Circuit's decision in this case jeopardizes Medicaid patients by sacrificing a vital safeguard—the formulary requirements of the federal Medicaid statute, SSA § 1927(d)(4)—that Congress established to protect their access to prescription drugs. Just as states are waiting to learn

whether they may emulate Maine's attempt to secure additional manufacturer financing for non-Medicaid programs, so they are waiting to learn whether they may emulate Florida's attempt to secure such additional financing for the Medicaid program itself. Here, as in *Concannon*, resolution of the question presented has enormous ramifications for the achievement of Congress's purposes under a major federal program. At a minimum, the Court should hold this petition for disposition following its decision in *Concannon*.

STATEMENT OF THE CASE

1. The Medicaid program provides medical assistance for the needy and is jointly financed and administered by the federal government and the states. *See* SSA tit. XIX, §§ 1901-1935, 42 U.S.C. §§ 1396-1396v. State Medicaid agencies reimburse health care providers for covered services to beneficiaries, and the federal government reimburses the states a portion of these expenditures. The federal government currently pays more than half of Florida's Medicaid costs.

SSA § 1927, 42 U.S.C. § 1396r-8, governs prescription drug coverage in the Medicaid program. The states reimburse pharmacists for the retail price of prescription drugs dispensed to Medicaid patients, and the federal government reimburses the states a portion of these expenditures. Manufacturers, in return for having their drugs covered by Medicaid, pay "rebates" to the federal and state governments to reimburse a portion of the price the federal and state governments pay to the pharmacists.

Subject to limited exceptions, the federal statute requires states to provide Medicaid coverage for all drugs of each manufacturer that has entered into a rebate agreement with the Secretary of the Department of Health and Human Services ("HHS"). SSA § 1927(c)(1) specifies the amount of the required manufacturer rebate, ensuring that the state will receive the manufacturer's "best price." In particular, the

statute specifies that the manufacturer's rebate must reduce the price of the drug to a price that is either (1) 15.1 percent below the average price charged by the manufacturer for the drug, or (2) the lowest price charged by the manufacturer for the drug to any commercial customer, whichever price is less.

SSA § 1927(d)(4) authorizes a state to create a state Medicaid drug "formulary"—a list of those drugs for which Medicaid coverage will be routinely provided in that state. The provision specifies that a state Medicaid formulary can be developed only by a special committee of qualified individuals comprised as specified in SSA § 1927(d)(4)(A). The provision further specifies that the formulary must include all drugs covered by a rebate agreement with the Secretary, unless the formulary committee has provided a clinical justification for excluding such a drug from the formulary "with respect to the treatment of a specific disease or condition for an identified population (if any)." SSA § 1927(d)(4)(B)-(C). In particular, the provision specifies that such a drug may not be excluded from the formulary unless the formulary committee has determined in writing that the excluded drug lacks "a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary." SSA § 1927(d)(4)(C).

Congress prohibited states from excluding drugs from a state Medicaid formulary—except where the requisite written determination of no "significant, clinically meaningful therapeutic advantage" has been made—in order to ensure that Medicaid patients would not be denied ready access to the most advantageous drugs based on non-clinical considerations, such as cost. Indeed, Congress in 1990 had prohib-

ited state Medicaid formularies altogether, in order to prevent states from restricting access to drugs on the basis of cost.[1] When Congress in 1993 restored the states' ability to establish Medicaid formularies, it prohibited them from excluding drugs except for clinical reasons.[2]

Even for a drug properly excluded from a formulary based on the required written clinical determination, the state must permit Medicaid coverage of the drug pursuant to a "prior authorization program" consistent with SSA § 1927(d)(5). SSA § 1927(d)(4)(D). SSA § 1927(d)(5) provides that a state may establish a "prior authorization program," requiring state "approval of [a] drug before its dispensing," only if the system provides for responses to requests for such approval within 24 hours and provides a 72-hour supply of the drug in emergency situations. *See also* SSA § 1927(d)(1) (specifying that a state may require prior authorization for covered drugs if the state complies with the requirements of SSA § 1927(d)(5)).

2. a. On May 31, 2001, Florida enacted the law challenged here: Chapter 2001-104 of the 2001 Florida Laws ("2001 amendments"), amending, *inter alia*, Fla. Stat. §§ 409.91195, 409.912. On no fewer than nineteen occasions (including three in the title of the statute), the statute describes its undertaking as the establishment of a "formulary," and on three of those occasions it does so with specific reference to the section of the federal Medicaid statute

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[1] Omnibus Budget Reconciliation Act of 1990, sec. 4401(a)(2)(C), Pub. L. No. 101-508, 104 Stat. 1388-143 (codified at 42 U.S.C.A. § 1396a(a)(54) (1992) (repealed 1993)).

[2] Omnibus Budget Reconciliation Act of 1993, sec. 13602(a), Pub. L. No. 103-66, 107 Stat. 312, 616-17 (codified at 42 U.S.C.A. § 1396r-8(d)(4) (1994)).

(SSA § 1927) that establishes requirements for state Medicaid formularies. The amendments, which became effective on July 1, 2001:

- authorized Florida's Agency for Health Care Administration ("AHCA") to "establish a preferred drug formulary in accordance with 42 U.S.C. s. 1396r-8 [SSA § 1927]," Fla. Stat. § 409.912(38)(a)(7);
- created within AHCA a Medicaid Pharmaceutical and Therapeutics Committee "for the purpose of developing a preferred drug formulary pursuant to 42 U.S.C. s. 1396r-8 [SSA § 1927]," Fla. Stat. § 409.91195;
- provided for this Committee to be comprised "as specified in 42 U.S.C. s. 1396r-8 [SSA § 1927]," Fla. Stat. § 409.91195(1); and
- provided that "reimbursement of drugs not included in the formulary is subject to prior authorization," Fla. Stat. § 409.91195(5).

For a drug to be considered for inclusion on the Florida "preferred drug formulary," the 2001 amendments require a manufacturer to pay the state a "supplemental rebate" sufficient to raise the combined federal and state rebates for the drug to at least 25 percent of the average manufacturer price (compared to the minimum 15.1 percent rebate specified by the federal statute). Fla. Stat. § 409.912(38)(a)(7). Moreover, payment of this supplemental rebate for a drug merely guarantees consideration of the drug for inclusion on "the preferred drug formulary"; it does not guarantee inclusion of the drug "on the formulary." *Id.* Drugs for which a manufacturer does not agree to pay this supplemental rebate are excluded from the formulary without any determination that they lack a "significant, clinically meaningful therapeutic advantage," SSA § 1927(d)(4)(C), over other drugs included on the formulary. "[D]rugs not included in the formulary"

are automatically "subject to prior authorization" before they may be prescribed. Fla. Stat. § 409.91195(5).

Before the 2001 amendments were enacted, Florida had a Pharmaceutical and Therapeutics Committee, but its membership was not "comprised as specified" in SSA § 1927, and it therefore was not qualified to develop a state Medicaid formulary under SSA § 1927(d)(4).[3] Under the preexisting Florida law, this Committee had developed a Voluntary Preferred Drug List ("VPDL"). Manufacturers were not required to pay supplemental rebates to have their drugs included on the VPDL, and physicians could prescribe drugs not included on the VPDL without obtaining prior authorization.

Until the state could appoint a new Medicaid Pharmaceutical and Therapeutics Committee "comprised as specified" in SSA § 1927, the 2001 amendments directed AHCA to use the VPDL and to require prior authorization for drugs not included on the VPDL. Fla. Stat. § 409.91195(8). To meet the July 1, 2001, effective date of the 2001 amendments, AHCA used the existing committee to recommend additions to and deletions from the VPDL. When AHCA finalized the interim formulary, it excluded 1,006 drugs for which manufacturers had entered into federal rebate agreements, or over 50 percent of all such drugs. (App. 42.) None of these drugs was excluded from the interim formu-

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[3] SSA § 1927(d)(4)(A) provides that a Pharmaceutical and Therapeutics Committee qualified to develop a state Medicaid formulary must consist of "physicians, pharmacists, and other appropriate individuals appointed by the Governor." Before 2001, the Florida law creating its committee had specified the appointment of the committee's physician members by the Speaker of the House and the President of the Senate. *See* Fla. Stat. § 409.91195(1) (2000).

lary based on the written, clinical determination specified in SSA § 1927(d)(4)(C).

After the 2001 amendments became effective, the Governor appointed a new Medicaid Pharmaceutical and Therapeutics Committee "comprised as specified" in SSA § 1927. At its first meeting on August 25, 2001, the reconstituted Committee approved and adopted the interim formulary established by the old Committee, again without making any clinical determinations, and again with the effect that all 1,006 excluded drugs are available only with prior authorization. (*Id.*)

b. Requiring prior authorization for drugs excluded from Florida's "preferred drug formulary" is intended to save the state money in two ways: (1) by inducing manufacturers to pay increased rebates to have their drugs included on the formulary, and thereby *avoid* prior authorization; and (2) by reducing the utilization of those drugs for which manufacturers, despite the threat of prior authorization, have not paid increased rebates. The 2001 amendments' prior authorization requirement had precisely this intended effect—sharply reduced utilization—on drugs excluded from Florida's formulary.

Under AHCA's prior authorization procedures, if a physician seeks to prescribe an excluded drug for a Medicaid patient, the physician must first call AHCA's contractor to request permission—a process that AHCA acknowledges requires an average of five to ten minutes of the physician's time for each prescription. (App. 2, 57.) (By comparison, according to the National Center for Health Statistics, the average doctor's visit between 1989 and 1998 was under

eighteen minutes.[4]) The physician must provide a clinical explanation of why the excluded drug is necessary for the particular patient. (App. 89.) And, if the state contractor disagrees, authorization will be granted only for a 30-day supply of drugs, and the physician may be required to provide further written clinical documentation. (App. 90.)

The result of the Florida regime, as reported by AHCA, has been a drastic decline in the utilization of drugs excluded from the formulary. (App. 16.) The court of appeals concluded that, following the enactment of the Florida legislation, "the Medicaid market share for drugs not on the preferred drug list has shrunk significantly." (App. 3.) Indeed, prior authorization regimes frequently result in a patient receiving no drug at all.[5]

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[4] David Mechanic et al., *Are Patients' Office Visits with Physicians Getting Shorter?*, 334 New Eng. J. Med. 198, 200 fig. 1 (2001).

[5] A recent study analyzed the effect of a different aspect of Florida's Medicaid program, which requires prior authorization for any prescription over a four-brand-drug-per-patient limit. Out of roughly 155,000 instances in which a pharmacy was informed that it could not fill a prescription because it would have exceeded the four-brand limit, the prescribing physician then declined to pursue prior authorization in about 60 percent of the cases. Some portion of that figure may represent cases in which the physician switched the patient to second-choice generic drugs rather than attempting to navigate through the prior authorization process. But the study reports that in over 25 percent of those cases, no drug was dispensed to the patient at all. *See* Mary Kay Owens et al., Fla. Ctr. for Medicaid Issues, *Florida Medicaid Prescribed Drug Program: Four Brand Prescription Limit Policy: Final Report—Phase I, June 2001* 4-5 (2001), *available at* http://www.vtmd.org/policy/team/T3-1-02-a.doc.

3. a. On August 7, 2001, PhRMA filed its complaint in the United States District Court for the Northern District of Florida seeking, *inter alia*, (1) a declaration that the 2001 amendments to Fla. Stat. §§ 409.91195 and 409.912 conflict with SSA § 1927(d)(4), and are therefore invalid under the Supremacy Clause and 42 U.S.C. § 1983; and (2) preliminary and permanent injunctive relief.

PhRMA argued that the 2001 amendments create a state Medicaid drug formulary that is subject to the requirements of SSA § 1927(d)(4) but unlawfully excludes drugs, without the clinical determination required by SSA § 1927(d)(4)(C), because a manufacturer has refused to pay a supplemental rebate. On August 31, 2001, the district court referred PhRMA's motion for preliminary injunctive relief to a magistrate judge.

b. Before PhRMA filed its lawsuit, AHCA had submitted to the Centers for Medicare and Medicaid Services ("CMS") of HHS proposed amendments to Florida's State Medicaid Plan, reflecting the changes made by the 2001 amendments.[6] In these proposed revisions, and in subsequent communications to CMS, AHCA insisted that the 2001 amendments created a Medicaid "preferred drug formulary with prior authorization" subject to SSA § 1927(d)(4). CMS insisted in response that what Florida had created did not meet the requirements of SSA § 1927(d)(4) for Medicaid formularies: "the state's use of the word 'formulary' [in its proposed plan amendment] doesn't meet the definition of formulary in Section 1927." (App. 13.) CMS suggested that AHCA rectify this problem by calling what the 2001 amendments had created by a dif-

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[6] The federal Medicaid statute requires a state participating in Medicaid to submit state plan amendments to CMS for approval. SSA § 1903(a), 42 U.S.C. § 1396b(a).

ferent name. It suggested that state officials "strike all references to 'formulary' from their state plan and replace them with another term/phrase such as 'preferred drug list.'" (*Id.*) AHCA resisted this suggestion and on August 8, 2001, resubmitted its plan amendments to CMS, continuing to refer to its "formulary." (App. 13-14.)

Following briefing on PhRMA's motion for preliminary injunction, AHCA—which had still not received CMS approval of its state plan amendments—abruptly reversed course and accepted CMS's suggestion that it rename its formulary a "prior authorization program." On September 14, 2001, days before the hearing on the motion before the magistrate judge, AHCA submitted to CMS further revised plan amendments, replacing the term "formulary" with "preferred drug list." (App. 14-15, 91.) Tellingly, however, AHCA retained in its plan amendments the sentence regarding appointment of a Pharmaceutical and Therapeutics Committee "to comply with" SSA § 1927. (App. 91.) CMS thereupon quickly approved the proposed amendments to Florida's State Medicaid Plan, on the eve of the hearing on PhRMA's preliminary injunction motion.

c. On September 20, 2001, the magistrate judge issued a report recommending that the district court deny PhRMA's motion for preliminary injunction on the ground that the 2001 amendments had not created a Medicaid drug formulary subject to SSA § 1927(d)(4), but instead had created a "prior authorization program" utilizing a "preferred drug list," which the magistrate judge found to be permitted by SSA § 1927(d)(5). On December 28, 2001, the district court adopted the magistrate's report, denied PhRMA's motion for a preliminary injunction and its cross-motion for summary judgment, and granted defendants' motion to dismiss or, in the alternative, for summary judgment.

4. On September 6, 2002, the Eleventh Circuit affirmed the district court's decision upholding Florida's supplemen-

tal rebate program. Relying heavily upon *PhRMA v. Concannon*, 249 F.3d 66 (1st Cir. 2001), *cert. granted*, 122 S. Ct. 2657 (2002) (No. 01-188), the Eleventh Circuit accepted AHCA's characterization of the 2001 amendments as creating a "prior authorization program" utilizing a "preferred drug list," and not as creating a state Medicaid formulary subject to the requirements of SSA § 1927(d)(4). The court then held that SSA § 1927(d)(1) and (5) permit this arrangement. (App. 19-23.)

The court reasoned that Florida law had not created a state Medicaid formulary *because* its program provided for the exclusion of drugs without the clinical determination required by SSA § 1927(d)(4)(C). In other words, what PhRMA presented as proof that the Florida program violates SSA § 1927(d)(4)'s formulary requirements, the Eleventh Circuit viewed as proof that the Florida program is not a formulary.

The Eleventh Circuit also viewed the 2001 amendments as a "prior authorization program," not as a Medicaid formulary, because Florida's imposition of prior authorization requirements merely "restricts," and does not "exclude," coverage of drugs not on the state's "preferred drug list." (App. 19-21.) The court understood a Medicaid formulary, by contrast, to "exclude," not merely "restrict," coverage of drugs not on the formulary. (*Id.*) The court interpreted SSA § 1927(d)(4) to permit non-formulary drugs to be *excluded* from Medicaid coverage, even though SSA § 1927(d)(4)(D) specifies that coverage of a drug excluded from a Medicaid formulary *must be permitted* with prior authorization. In considering the interplay between SSA § 1927(d)(4) and SSA § 1927(d)(1) and (5), the court of appeals declined to consider the legislative history of these provisions because it viewed the statutory language as clear. (App. 26-27.)

REASONS FOR GRANTING THE WRIT

1. In its *amicus* brief to this Court in *Concannon* (No. 01-188), to be argued on January 22, 2003, the United States has stated that the question presented by this case merits the Court's attention. The United States has invited the Court to decide in *Concannon* the very question presented here—whether SSA § 1927(d)(4) limits a state's ability to impose broad restrictions on Medicaid patients' access to a manufacturer's drugs, unless the manufacturer has agreed to pay the state a greater rebate than the rebate specified in the federal statute. That question, however, was neither presented nor decided in *Concannon*. It is squarely presented here. This case, not *Concannon*, provides the appropriate occasion for considering that question. (*See infra* pp. 14-16.)

2. Whether the federal Medicaid statute allows states to impose broad restrictions on Medicaid patients' access to prescription drugs, in order to obtain extra Medicaid rebates from manufacturers, is an important question of federal law that this Court should settle. The answer to this question will determine whether the patient safeguards in SSA § 1927(d)(4) are illusory—the result of the Eleventh Circuit's decision—or real. The issue is plainly of national importance, and this Court's guidance is urgently required. Florida was only the first state to seek to reduce its Medicaid prescription drug costs by restricting Medicaid patients' access to drugs, unless manufacturers agree to pay extra Medicaid rebates. Several other states have since followed suit, and others are waiting in the wings. (*See infra* pp. 17-19.)

3. Contrary to the Eleventh Circuit's decision, the federal Medicaid statute does not allow a state to impose broad restrictions on Medicaid patients' access to prescription drugs to obtain extra manufacturer rebates in Medicaid. The imposition of such access restrictions amounts to the creation of a state Medicaid formulary; and if a state creates a

Medicaid formulary, it may not exclude drugs from routine coverage without making the clinical determinations required by SSA § 1927(d)(4)(C). If states could establish "preferred drug lists" indistinguishable from Medicaid formularies, without satisfying the Medicaid statute's requirements for such formularies, the formulary requirements of the federal statute, through which Congress aimed to protect Medicaid patients' access to prescription drugs, would be a dead letter. (*See infra* pp. 19-26.)

4. At a minimum, because the Eleventh Circuit relied on *Concannon*, and because *Concannon* does present one issue also presented by this case—whether a state's power to impose "prior authorization" requirements under the federal statute, SSA § 1927(d)(1), (5), is unconstrained by other provisions of the Medicaid statute—the petition should at least be held for consideration pending the Court's disposition of that case. (*See infra* pp. 26-27.)

I. The United States Has Invited the Court To Decide the Question Presented by this Case.

In its *amicus* brief filed in *Concannon* (No. 01-188), the United States has invited the Court to address the issue presented by this case: whether the federal Medicaid statute's formulary provision, SSA § 1927(d)(4), limits a state's ability to use prior authorization to compel manufacturers to pay supplemental rebates on drugs prescribed to Medicaid recipients. Brief for the United States as *Amicus Curiae* Supporting Reversal at 17, *Concannon* (No. 01-188). This Court should address that important question of federal law; but this case, not *Concannon*, properly presents the question.

In *Concannon*, PhRMA challenged a Maine prescription drug program, known as "Maine Rx," that uses the threat of Medicaid prior authorization to induce drug manufacturers to pay the state a Medicaid-level rebate to subsidize prescription drug purchases by *non*-Medicaid participants. The Court granted certiorari on two questions:

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq.*, allows a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations?

2. Whether a state may circumvent the Commerce Clause prohibition against regulating or taxing wholly out-of-state transactions by requiring an out-of-state manufacturer, which sells its products to wholesalers outside the state, to pay the state each time one of its products is subsequently sold by a retailer within the state?

Petition for a Writ of Certiorari at i, *Concannon* (No. 01-188). Supporting PhRMA, the United States argues in *Concannon* that the Maine Rx program is invalid because it restricts Medicaid patients' access to drugs to advance non-Medicaid goals. Brief for the United States at 10, *Concannon* (No. 01-188).

The United States also asserts, however, that "A State May Require Prior Authorization For Prescription Drugs In Order To Achieve Cost Savings Under Its Medicaid Program." *Id.* at 14. It claims that the federal Medicaid statute's formulary provision, SSA § 1927(d)(4), "furnish[es] no basis for limiting a State's ability to establish a prior authorization program in order to obtain additional drug rebates for Medicaid recipients." Brief for the United States at 18, *Concannon* (No. 01-188). Indeed, directly addressing this case, the United States disputes PhRMA's contention here that "the Florida . . . program [is] not [a] valid prior authorization program[ ], but rather in effect establish[es a] formular[y] that fail[s] to comply with the requirements of 42 U.S.C. 1396r-8(d)(4)(C)." *Id.* at 17. The United States asserts that PhRMA's contention with respect to the Florida program is "without merit." *Id.*; *see also id.* at 17-18 ("[A]s

the Secretary has reasonably concluded, a State has the authority to establish a prior authorization program *without* meeting the requirements applicable to formularies.").

But *Concannon* does not present the question presented in this case—the limitations imposed by the formulary requirements of SSA § 1927(d)(4) on a state's ability to compel manufacturers to pay supplemental rebates on drugs prescribed to Medicaid patients. *Concannon* instead involves a state's attempt to use its Medicaid powers to compel manufacturers to finance Medicaid-level discounts for individuals outside of Medicaid. The formulary requirements of SSA § 1927(d)(4), and the state's ability to secure supplemental Medicaid rebates, are not at issue in *Concannon*. These issues were neither raised by the parties in that case nor decided by either the district court or the court of appeals. *Concannon*, accordingly, does not present an appropriate occasion to consider them. *See Nat'l Collegiate Athletic Ass'n v. Smith*, 525 U.S. 459, 470 (1999) ("[W]e do not decide in the first instance issues not decided below.") (issue raised for the first time in this Court by the United States as *amicus*, together with respondent); *Penn. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212-13 (1998) ("Where issues are neither raised before nor considered by the Court of Appeals, this Court will not ordinarily consider them.") (quoting *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 147 n.2 (1970) (citations omitted)).

These issues were decided below and are squarely presented in this case. The United States has recognized that they merit this Court's consideration, and the Court should grant this petition to address them.

II. Whether the Federal Medicaid Statute Allows States To Impose Broad Restrictions on Medicaid Patients' Access to Prescription Drugs To Obtain "Supplemental" Medicaid Rebates from Manufacturers Is an Important Question of Federal Law that this Court Should Settle.

Florida was the first state to attempt to reduce its Medicaid prescription drug costs by broadly restricting Medicaid patient access to prescription drugs in order to secure extra manufacturer rebates for the Medicaid program. Many other states have adopted, or are moving forward with, similar programs.

In March 2002, Michigan implemented a program generally requiring prior authorization for any Medicaid drugs for which a manufacturer has not entered into a supplemental rebate agreement.[7] The Vermont legislature in June 2002

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[7] *See* Transmittal and Notice of Approval of State Plan Material, *at* http://cms.hhs.gov/medicaid/stateplans/state_data/mi/spa/mi01_015.pdf (last visited Nov. 25, 2002) (CMS approval of Michigan supplemental rebate agreement). PhRMA and patient groups have filed actions in state and federal court challenging the Michigan program. In the state court action, PhRMA and the patient groups challenge the Michigan program on state constitutional and statutory grounds. On January 9, 2002, the Michigan Circuit Court of Ingham County granted plaintiffs' motion for a preliminary injunction, but the Michigan Court of Appeals stayed the circuit court's order pending Michigan's appeal. The appeal was argued on September 5, 2002, and the parties are awaiting the court of appeals' ruling. *PhRMA v. Mich. Dep't of Cmty. Health*, No. 01-94627-AZ (Ingham Cty. Cir. Ct.), *appeal pending*, No. 238862 (Mich. Ct. App.). In their federal court action, PhRMA and the patient groups claim that the Secretary of HHS exceeded his authority in approving the Michigan program because the program violates the requirements of the federal Medicaid statute. (continued...)

directed the state Medicaid agency to establish a "preferred drug list" with "a prior authorization review process," Vt. Stat. Ann. tit. 33, § 1998(a)(1)-(2); authorized "a supplemental rebate program," *id.* § 1998(a)(3); and explicitly directed the state commissioner to consider the "strategy used by the State of Florida to secure supplemental rebates," *id.* § 2002(b). New Mexico took similar steps in March 2002. *See* N.M. Stat. Ann. § 27-2C-3 to -4 (authorizing a "formulary or preferred drug list").

Several other states are proceeding with similar programs at various stages of completion. *See* Nat'l Conf. of State Legislatures, *Recent Medicaid Prescription Drug Laws and Strategies, 2001-2002*, *at* http://www.ncsl.org/programs/health/medicaidrx.htm (updated Nov. 11, 2002) (detailing state Medicaid prescription drug law changes). Moreover, CMS in September 2002 issued an informal statement that purports to give these programs a green light; a development that will only accelerate this trend.[8]

Plaintiffs' motion for preliminary injunction was argued on August 28, 2002, and the parties are awaiting the district court's ruling. *PhRMA v. Thompson*, No. 02-CV-1306 (D.D.C. filed June 28, 2002).

[8] CMS announced that "[s]tates may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients." Letter from Dennis G. Smith, Director, Center for Medicaid and State Operations, CMS, to State Medicaid Directors (Sept. 18, 2002), *at* http://cms.hhs.gov/states/letters/smd91802.pdf. Although that CMS statement is not entitled to deference, *see Christensen v. Harris County*, 529 U.S. 576, 586-87 (2000), it will surely encourage other states to emulate Florida, and suggests that CMS will approve the programs of the states that do so.

States at various stages of adopting provisions similar to Florida's will look to this case to determine the legality of those programs. States adopting programs different from Florida's will also look to this case to determine the future course of their initiatives and the viability of potential adjustments. It is important that this Court clarify whether states may enforce supplemental Medicaid rebate requests by using their prior authorization powers in a way that evades the requirements of SSA § 1927(d)(4).

III. The Federal Medicaid Statute Does Not Allow a State To Impose Broad Restrictions on Medicaid Patients' Access to Prescription Drugs To Obtain "Supplemental" Medicaid Rebates from Manufacturers.

"Once a State voluntarily chooses to participate in Medicaid, the State must comply with the requirements of Title XIX and applicable regulations." *Alexander v. Choate*, 469 U.S. 287, 289 n.1 (1985); *accord Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 501 (1990). Whatever the name used, Florida's 2001 amendments create a state Medicaid drug formulary subject to the requirements of SSA § 1927(d)(4)—a formulary that unlawfully excludes drugs because a manufacturer has refused to pay the state a supplemental rebate, without the clinical determination required by SSA § 1927(d)(4)(C).

There is no distinction between what Florida has created and a Medicaid formulary—except for Florida's unlawful exclusion of drugs for cost rather than clinical reasons.

Florida's list of covered drugs was established by a Pharmaceutical and Therapeutics Committee comprised as specified in SSA § 1927(d)(4)(A); the list includes all drugs covered by rebate agreements with the Secretary of HHS, except for those that are excluded, *see* SSA § 1927(d)(4)(B); and the program provides for coverage of excluded drugs with prior authorization, *see* SSA § 1927(d)(4)(D). The *only* respect in which the Florida program is *not* like a Medicaid

formulary is in its exclusion of drugs, based not on the clinical determinations required by SSA § 1927(d)(4)(C), but on a manufacturer's unwillingness to pay supplemental rebates. The Florida Legislature erred in supposing that it could create a Medicaid formulary from which drugs could be excluded without such clinical determinations. But it is clear that the Florida Legislature created a Medicaid formulary within the meaning of SSA § 1927(d)(4).[9]

The Eleventh Circuit acknowledged that when a state creates a Medicaid formulary, it cannot "consider a drug's 'cost-effectiveness'" because "the governing federal statute clearly limits such decisions to clinical issues of safety and drug effectiveness." (App. 19.) But the court erroneously concluded that Florida had *not* created a formulary based on the court's mistaken view that a formulary "has the effect of *excluding* coverage of, or payment for, certain Medicaid-eligible drugs," (App. 9), whereas the Florida program "merely *conditions* coverage for non-preferred drugs on whether the prescribing physician has followed the prior authorization procedure," (App. 27-28). That is, the court concluded, erroneously, that Florida had not created a Medicaid formulary because (the court mistakenly believed) a state Medicaid formulary would exclude non-formulary drugs from Medicaid coverage, whereas Florida claims that

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[9] This Court is not bound by the Eleventh Circuit's erroneous conclusion that the 2001 amendments purported to create something other than a Medicaid formulary. *See generally Brockett v. Spokane Arcades, Inc.*, 472 U.S. 491, 500 (1985) ("The rule [of deference to courts of appeals' interpretations of state law] is not ironclad . . . and we surely have the authority to differ with the lower federal courts as to the meaning of a state statute."). For the reasons discussed above, moreover, what the 2001 amendments created is a formulary in substance and effect, notwithstanding the terminology adopted *post hoc* by Florida.

its program guarantees coverage of drugs not on the state's list, as long as the physician "has followed the prior authorization procedure." (App. 28.)

That distinction cannot be reconciled with the language of the Medicaid statute. The federal statute *requires* that "[t]he State plan permit[ ] coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program." SSA § 1927(d)(4)(D). The availability of excluded drugs through a prior authorization program is a *legally required attribute* of a formulary. The *presence* of a prior authorization component thus cannot be interpreted as proof that the program is *not* a Medicaid formulary. Nor can it be understood to eliminate the need to comply with the requirement of SSA § 1927(d)(4)(C).[10]

Under the court's interpretation of SSA § 1927(d)(5), a state could *never* violate SSA § 1927(d)(4)(C): the very fact that a state had excluded drugs for cost reasons, as Florida did here, rather than on the basis of clinical determinations, would be proof that it had not adopted a formulary, but had adopted a prior authorization program instead.

The court's interpretation, if allowed to stand, would render SSA § 1927(d)(4) a dead letter. No state would ever create a formulary and subject itself to the limitations that Congress so carefully prescribed for formularies, if a state can achieve the same effect, without subjecting itself to

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[10] The Eleventh Circuit also sought to distinguish a prior authorization program from a formulary on the ground that under a formulary the ultimate decision about whether a drug will be covered rests with the state, but under a prior authorization program that decision rests with the physician. (App. 27-28.) The court cited no support for that distinction, and the federal statute provides no such support.

those limitations, simply by calling what it has created by a different name. Rather than undertake the clinical determinations required by SSA § 1927(d)(4)(C), a state would instead simply purport to be exercising its "prior authorization" powers under SSA § 1927(d)(1) and (5). This interpretation of SSA § 1927(d)(1) and (5) violates the cardinal rule that a statute should be interpreted as a whole and not in a manner that renders any part (here, the formulary provision) inoperative. *See Mountain States Tel. & Tel. Co. v. Pueblo of Santa Ana*, 472 U.S. 237, 249 (1985) ("[A] statute should be interpreted so as not to render one part inoperative.") (quoting *Colautti v. Franklin*, 439 U.S. 379 (1979)); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000) ("[A] reviewing court should not confine itself to examining a particular statutory provision in isolation" but must instead "interpret the statute as a symmetrical and coherent regulatory scheme.") (internal quotation marks omitted). The Eleventh Circuit's construction of SSA § 1927(d)(1) and (5) must not be allowed to stand.[11]

The last sentence of SSA § 1927(d)(4) does make clear that not every prior authorization program is a formulary. For example, many states (including Florida) require prior approval before a Medicaid recipient can receive more than a specified number of prescriptions in any given month,[12]

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[11] CMS certainly has no power to waive the requirements of SSA § 1927(d)(4), and this Court's decision in *Wilder* establishes that federal approval of a state plan does not mean that the plan meets the requirements of the federal Medicaid statute. *See* 496 U.S. at 521-22 (holding that health care providers could challenge a state's HHS-approved method for reimbursing them).

[12] *See, e.g.*, Fla. Stat. § 409.912(38)(a)(1) (more than four prescriptions); Miss. Code § 43-13-117(9)(b) (more than five prescriptions); N.J. Admin. Code tit. 10, § 51-11.14(b)(6) (more than seven prescriptions).

and states may impose prior authorization to combat fraud or abuse, SSA § 1927(d)(6). But these kinds of prior authorization requirements do not purport to dictate that one of several alternative drugs will be given preferential standing for the treatment of a given medical need, with the rest available only if prior authorization can be obtained. That is what the Florida regime does, with respect to nearly 2000 different prescription drugs, in dozens of therapeutic classes covered by Medicaid. That is what transforms Florida's program into a formulary subject to SSA § 1927(d)(4).

In enacting SSA § 1927(d)(4), Congress meant to ensure that states would not draw such distinctions unless the state's expert committee (comprised as dictated by Congress) had determined in writing that another formulary drug is clinically equivalent or superior. The Florida regime vitiates this carefully constructed federal policy.

The legislative history of SSA § 1927 confirms that a state may not use its prior authorization program to impose broad access restrictions on drugs for cost-saving purposes.[13] Before 1990, the federal Medicaid statute did not require manufacturers to pay rebates, nor did it constrain states' ability to limit prescription drug coverage through formularies or prior authorization requirements.[14] To control costs, many states established formularies similar to the

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[13] The Eleventh Circuit declined to consider this legislative history on the basis of its view that the statutory language was clear. (App. 26-27.)

[14] *See* H.R. REP. NO. 101-881, at 95 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2107; *Hearing on S. 2605 and S. 3029 Before the Subcomm. on Health for Families and the Uninsured of the Senate Comm. on Finance*, 101st Cong., 2d Sess. 26 (1991) (statement of Gail R. Wilensky, Ph.D., Administrator, HCFA); *id.* at 258 (prepared statement of Gail R. Wilensky).

formulary created by the 2001 amendments challenged here: lists of drugs for which coverage was routinely provided, with coverage for more expensive, excluded drugs provided only if prior authorization can be obtained.[15]

When Congress enacted SSA § 1927 in 1990, it sought to protect Medicaid patient access to prescription drugs by barring states from maintaining drug formularies.[16] In place of these formularies, Congress established the system that prevails today, under which Medicaid coverage of a manufacturer's drugs is guaranteed if the manufacturer pays the specified Medicaid rebate. Although Congress barred the states from maintaining Medicaid formularies, it did not bar them from continuing to impose prior authorization requirements. Instead, it allowed them to continue imposing such requirements, recognizing that states were applying such requirements to an "extremely small" number of prescription drugs.[17]

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[15] *See* 136 CONG. REC. 30485, 30515 (1990); *Hearing on S. 2605 and S. 3029* at 10 (statement of Rep. Wyden); *id.* at 19 (statement of Rep. Cooper); *id.* at 118 (attachment to prepared statement of Nancy W. Dickey, M.D., member, Bd. of Trustees, AMA); *id.* at 256-57 (table 3 of prepared statement of Judith L. Wagner, Ph.D., Senior Associate, OTA).

[16] Omnibus Budget Reconciliation Act of 1990, sec. 4401(a)(2)(C), Pub. L. No. 101-508, 104 Stat. 1388-143 (codified as amended at 42 U.S.C.A. § 1396a(a)(54) (1992) (repealed 1993)); *see* H.R. REP. NO. 101-881 at 96-97.

[17] *Hearing on S. 2605 and S. 3029* at 225 (attachment to prepared statement of Sen. Pryor titled *Responses to Common Questions and Concerns Raised in September 17, 1990 Senate Finance Committee Hearing About S. 2605 and S. 3029, prepared by the staff of the U.S. Senate Special Committee on Aging*):

(continued...)

In continuing to allow states to impose prior authorization requirements when it abolished state formularies in 1990, Congress obviously did not mean to allow states to achieve through such requirements the same results as those achieved through the formularies, which Congress had just prohibited. And when Congress amended SSA § 1927 in 1993 to restore the states' ability to establish drug formularies,[18] it took pains to prevent the states from undermining the earlier-established patient access protections, by requiring that all drugs covered by Medicaid be included on a formulary unless determined to be no more clinically advantageous than other drugs included on the formulary.[19] Congress would have had no need to restore the states' ability to

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> As of September 1990, 25 state Medicaid programs required some form of prior authorization for an extremely small number of prescription drug products or over-the-counter (non-prescription) drug products. In general, prior approval programs are used by many states—for a very small percentage of Medicaid-covered prescription drugs—to assure that the prescriptions dispensed are medically necessary.
>
> . . . The states have asked for the flexibility . . . to retain their *current* ability to use prior approval for a small number of drugs even if they are given rebates.

[18] Omnibus Budget Reconciliation Act of 1993, sec. 13602(c), Pub. L. No. 103-66, 107 Stat. 312, 619 (codified at 42 U.S.C.A. § 1396a(a)(54) (1994)).

[19] *Id.* sec. 13602(a), 107 Stat. at 616-17 (codified at 42 U.S.C.A. § 1396r-8(d)(4) (1994)); *see* H.R. REP. NO. 103-111, at 204-06 (1993); H.R. CONF. REP. No. 103-213, at 833 (1993); Senate Comm. on the Budget, 103d Cong., *Reconciliation Submissions of the Instructed Committees Pursuant to the Concurrent Resolution on the Budget (H. Con. Res. 64)* 139-40 (Comm. Print 1993).

establish drug formularies, and no purpose would have been served by imposing the clinical determination safeguard of SSA § 1927(d)(4)(C), if states *already* had the power to use prior authorization requirements to restrict patient access without satisfying that safeguard.

The Florida program, and the others like it, violate the limitations that Congress carefully imposed, and review by this Court is warranted.

IV. At a Minimum, the Court Should Hold the Petition Pending Disposition of *Concannon*.

The issues presented in this case and *Concannon* are distinct. (*See infra* pp. 14-16.) Nonetheless, the Eleventh Circuit relied on *Concannon* at several points in its decision, and it was the only case cited when the court reached its interpretation of SSA § 1927(d)(5). (App. 6, 18, 19, 23.) For this reason, the Court's disposition of *Concannon* could affect an underpinning of the Eleventh Circuit's decision, such that an order granting certiorari and vacating the judgment below may be warranted.

Furthermore, the Eleventh Circuit decision here and the First Circuit's in *Concannon* do share a common feature: both read the prior authorization provisions in SSA § 1927(d)(1) and (5) to allow a state to use prior authorization for any purpose whatsoever, free of the strictures that the other provisions of the federal statute impose. In *Concannon*, the First Circuit held that a state could use prior authorization to obtain Medicaid-level rebates from manufacturers for non-Medicaid programs, 249 F.3d at 75-76, notwithstanding, *inter alia*, the requirement that a state operate its Medicaid program "consistent with . . . the best interests of *the* [*Medicaid*] *recipients*." 42 U.S.C. § 1396a(a)(19) (emphasis added). Here, the Eleventh Circuit held a state could use its prior authorization powers without regard to the federal statute's formulary requirements, even when the state openly acknowledged that it was engaged in the crea-

tion of a formulary, and what the state created, regardless of the name used, was a formulary in substance and effect. A ruling by this Court in *Concannon* that SSA § 1927(d)(1) and (5) must be construed *in pari materia* with the other provisions of the Medicaid statute, and may not be read in isolation or in a manner that disregards other statutory objectives, would have direct implications for this case.

Accordingly, for the reasons stated earlier, the Court should grant the petition and reverse. At a minimum, however, the Court should hold the petition until it decides *Concannon* and then grant the petition and either review the Eleventh Circuit's decision, or vacate the Eleventh Circuit's decision and remand for further proceedings.

CONCLUSION

For the foregoing reasons, the petition should be granted. Alternatively, the petition should be held pending this Court's disposition of *Concannon*.

Respectfully submitted,

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December 5, 2002

APPENDIX

App. 1

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 02-10151

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff-Appellant,
v.
RHONDA M. MEADOWS, Bob Sharpe, Deputy Secretary of Medicaid Agency for Health Care Administration of the State of Florida,
Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of Florida.
Hon. William H. Stafford, District Judge.

Before
Birch, Marcus and Cudahy*, *Circuit Judges.*

David H. Remes, Steven J. Rosenbaum, Laura B. Gasho, Covington & Burling, Washington, D.C., and *Martha Harrell Chumbler*, Tallahassee, FL, were on brief for appellant.

Christa E. Calamas, William H. Roberts, Steven Alfons Grigas, Gregory J. Philo, Agency for Health Care Administration, and *Gary J. Anton*, Stowell, Anton & Kraemer, Tallahassee, FL, were on brief for defendants-appellees.

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* Honorable Richard D. Cudahy, U.S. Circuit Judge for the Seventh Circuit, sitting by designation.

Harold F.X. Purnell, Rutledge, Ecenia, Underwood & Purnell, P.A., Tallahassee, FL, for Womenheart and Florida Transplant Survivors Coalition, amici curiae.

Richard A. Samp, Washington Legal Foundation, Washington, DC, for Washington Legal Foundation and Allied Educational Foundation, amici curiae.

Thomas G. Schultz, Harold Eugene Lindsey, Joseph Beeler, P.A., Miami, FL, for Florida House of Representatives, amici curiae.

September 6, 2002

CUDAHY, *Circuit Judge.* The Florida legislature recently added another chapter in the ongoing efforts of states to hold down their Medicaid drug costs. The new Florida law enacted changes in its Medicaid program by creating a "preferred drug formulary" (also referred to as a "preferred drug list"), which exempts certain Medicaid-eligible drugs from a "prior authorization" requirement. If a drug is not on the preferred list, the prescribing doctor must call a state pharmacist to obtain approval of its use. In the course of this procedure, the pharmacist informs the doctor of the availability of other drugs (usually on the preferred drug list) that allegedly have comparable therapeutic value but are less expensive. The actual phone calls tend to be relatively brief (usually less than 10 minutes in length), and approval of the prescribing doctor's first-choice drug is guaranteed in 100 percent of all cases, provided only that he or she make the telephone call. During the first three months of the program, approximately 55 percent of all these calls have resulted in a change of the prescription to a drug on the preferred drug list. Naturally, because this procedure may tend

to promote less profitable drugs at the expense of more profitable ones, it is not favored by the pharmaceutical manufacturers that brought this lawsuit.

The prior authorization program gives the state of Florida considerable leverage in negotiating with pharmaceutical companies. Following its enactment, the Medicaid market share for drugs not on the preferred drug list has shrunk significantly. Companies that have agreed to pay a "supplemental rebate" to reduce or offset the state's Medicaid expenditures are guaranteed the right to have their products considered for the preferred drug list. And, as noted, preferred drugs are *exempt* from the prior authorization program. Currently, slightly less than half of all Medicaid-eligible drugs are included on Florida's preferred drug list.

Shortly after the Florida law went into effect, the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade group, sued the Agency for Health Care Administration (AHCA), which is the Florida agency that administers the state Medicaid program. The PhRMA alleged that the preferred drug provision was a "formulary" within the meaning of 42 U.S.C. § 1396r-8(d)(4). Since the Florida law did not satisfy all the requirements of that statute for a Medicaid formulary, the PhRMA argued that Florida's preferred drug list and prior authorization provisions were preempted by federal law. On cross-motions for summary judgment, the district court ruled that the Florida law was a permissible application of § 1396r-8(d)(1)(A), (d)(5), which expressly authorizes prior authorization programs. The court therefore granted summary judgment for the AHCA. The PhRMA subsequently filed this appeal. We now affirm.

I.

Both the PhRMA and the AHCA agree that the material facts of this case are not in dispute. Therefore, this case ultimately turns on questions of statutory interpretation, which

we review de novo. *See United States v. DBB, Inc.*, 180 F.3d 1277, 1281 (11th Cir. 1999); *Haynes Ambulance Svc., Inc. v. State of Alabama*, 36 F.3d 1074, 1075 (11th Cir. 1994). The central issue is whether there is a conflict between the recently enacted Florida law and the governing federal Medicaid statute, 42 U.S.C. § 1396r-8. The state of Florida argues that the new Florida law, ch. 2001-104, codified at Fla. Stat. § 409.91195, 409.912, provides for a "prior authorization program" within the meaning of 42 U.S.C. § 1396r-8(d)(1)(A), (d)(5). In contrast, the PhRMA contends that the same provisions contemplates a "formulary" within the meaning of § 1396r-8(d)(1)(B)(iv), (d)(4).

Before commencing our analysis, we must discuss the relevant provisions of the federal Medicaid statutes and the new Florida law. We note at the outset that questions of statutory interpretation begin "by examining the text of the statute to determine whether its meaning is clear." *Harry v. Marchant*, 291 F.3d 767, 770 (11th Cir. 2002) (en banc) (citing *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438, 119 S. Ct. 755, 142 L. Ed. 2d 881 (1999)). "In construing a statute we must begin, and often should end as well, with the language of the statute itself." *United States v. Steele*, 147 F.3d 1316, 1318 (11th Cir. 1998) (en banc) (quoting *Merritt v. Dillard Paper Co.*, 120 F.3d 1181, 1185 (11th Cir. 1997)).

A.

Congress enacted the Medicaid program in 1965 in an effort to assist states with the cost of providing health care for the poor. Although the federal government provides approximately 56 percent of Florida's Medicaid funds, *see* 65 Fed. Reg. 69560-61, actual Medicaid relief is administered through state agencies pursuant to a Medicaid program that has been submitted to and approved by the U.S. Department of Health and Human Services. This cooperative venture between the federal and state governments is governed by

the terms of Title XIX of the Social Security Act (SSA), §§ 1901-1935, codified at 42 U.S.C. §§ 1396-1396v. In addition, every state in the nation currently operates its own Medicaid program under its own statutes.

One large and growing part of the Medicaid program is the coverage of outpatient prescription drugs. Under 42 U.S.C. § 1396r-8, a drug is eligible for Medicaid coverage only if its manufacturer enters into an agreement with the Secretary of the Department of Health and Human Services to make a specified rebate on each covered drug. With a few limited exceptions, this rebate is set by statute at 15.1 percent of the average manufacturer price. *See* § 1396r-8(c)(1) (setting 15.1 percent as the "minimum rebate percentage" for any rebate period commencing after December 31, 1995); § 1396r-8(k)(1) (defining the term "average manufacturer price"). The states, of course, are interested in securing additional rebates, and this is where the Florida legislature enters the picture.

Under 42 U.S.C. § 1396r-8(d)(1), state Medicaid agencies can impose additional "restrictions" on the coverage of Medicaid-eligible drugs. One provision of this statute, subsection (d)(1)(A), permits a "prior authorization program" for any covered outpatient drug. A second provision, subsection (d)(1)(B), permits various mechanisms for the exclusion or restricted coverage of outpatient drugs, including the creation of a "formulary" that meets certain statutory criteria.

The AHCA maintains that the new Florida law provides for a "prior authorization program." Under the applicable provision, "A State may subject to prior authorization *any* covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." § 1396r-8(d)(1)(A) (emphasis added). Paragraph (5), entitled "Requirements of prior authorization programs," reads as follows:

> A State plan under this subchapter may require (*as a condition of coverage or payment*) for a covered outpatient drug for which Federal financial participation is available in accordance with this section, . . . the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval—
>
> > (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
> >
> > (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

42 U.S.C. § 1396r-8(d)(5) (emphasis added). Under the plain language of this statute, *any* covered outpatient drug can be made subject to a prior authorization program if two requirements are met: (1) a response is provided within 24 hours of the request; and (2) a 72-hour supply of the drug is made available in emergency situations. In *Pharmaceutical Research & Manufacturers of America v. Concannon*, 249 F.3d 66, 76 (1st Cir. 2001), the First Circuit adopted this same interpretation of a § 1396r-8(d)(5) prior authorization program. At present, *Concannon* is the only other appellate opinion that has addressed this issue. However, during the pendency of this appeal, the Supreme Court granted a writ of certiorari in *Concannon*. *See Pharmaceutical Research & Mfrs. of Am. v. Concannon*, ___ U.S. ___, 122 S. Ct. 2657, 153 L. Ed. 2d 833 (2002).

In contrast to the interpretation proffered by the AHCA, the PhRMA contends that the new Florida law contemplates a "formulary," which is therefore subject to a requirements of § 1396r-8(d)(1)(B), (d)(4). Under these provisions, "A State may exclude or otherwise restrict coverage of a covered outpatient drug if . . . (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4)." § 1396r-8(d)(1)(B). The relevant parts of paragraph (4), entitled "Requirements for formularies," read as follows:

> A State may establish a formulary if the formulary meets the following requirements:
>
> > (A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State . . . .
> >
> > (B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section [which pertains to the rebate agreement required for Medicaid eligibility] . . . .
> >
> > (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is

> a written explanation (available to the public) of the basis for the exclusion.
>
> (D) The State plan permits coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program that is consistent with paragraph (5).
>
> (E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

§ 1396r-8(d)(4).

One important feature of subsection (d)(4)(D) of the quoted text is that, for drugs excluded from the formulary, a state must permit coverage pursuant to "a prior authorization program that is consistent with paragraph (5)." Paragraph (5) is the provision that outlines the 24-hour response and the 72-hour emergency drug-supply requirements of a prior authorization program. However, in order to clarify that a prior authorization program and a formulary are distinct methods of restricting coverage of outpatient drugs, the last sentence of subsection (d)(4) ends with the following proviso: "A prior authorization program established by a State under paragraph (5) *is not a formulary* subject to the requirements of this paragraph." § 1396r-8(d)(4) (emphasis added).

When comparing the statutory requirements of a "prior authorization program" with the statutory requirements that apply to a "formulary," one begins with the general principle that a state can impose, as a *condition* of Medicaid coverage or payment, that it be contacted prior to the dispensing of *any* covered outpatient drug. *See* § 1396r-8(d)(1)(A). If a state intends to operate a prior authorization program, that

program must provide for (1) a response within 24 hours, and (2) the availability of 72-hour emergency supply. *See* § 1396r-8(d)(5). By way of contrast, a state can take the more stringent course of creating a "formulary," which has the effect of *excluding* coverage of, or payment for, certain Medicaid-eligible drugs. *See* § 1396r-8(d)(1)(B). In addition, the "formulary" must fully comply with five specific requirements set forth in § 1396r-8(d)(4), which, among other things, generally limit an exclusion decision to issues of clinical safety and effectiveness. *See* § 1396r-8(d)(4)(C).

B.

In the spring of 2001, the Florida legislature passed the law that forms the basis of the present controversy. *See* Laws of Florida, § 2001-104 ("the 2001 amendments"), amending Fla. Stat. §§ 409.91195, 409.912.[1] After Governor Bush signed the bill, the Florida law went into effect on July 1, 2001. As a Medicaid reform measure that addressed the issue of covered outpatient drugs, the Florida law was presumably designed to operate against the existing backdrop of federal Medicaid statutes. In fact, the 2001 amendments explicitly reference the 42 U.S.C. § 1396r-8—the provision that prescribes circumstances under which a state Medicaid plan can restrict coverage of Medicaid-eligible outpatient drugs.

Unfortunately, the terminology adopted by the Florida law has at least two ambiguities that have produced the current controversy. First, section 409.91195 mandates the creation of a "preferred drug formulary," which seems to be an imprecise parallel to a "formulary" within the meaning of § 1396r-8(d)(1)(B)(iv), (d)(4). Second, the term "preferred

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[1] The text of §§ 409.91195, 409.912(37) are reproduced in an appendix to this opinion.

drug formulary" is used interchangeably throughout section 409.91195 with the term "preferred drug list."[2] The reference to a "preferred" drug list or "preferred" drug formulary appears to be unique to the Florida statute, since the term "formulary" in § 1396r-8 is not modified by any adjectives, much less a synonym for "preferred." Further, it is noteworthy that "formulary" is not a term of art that is specific to the requirements of § 1396r-8(d)(4). Webster's New Collegiate Dictionary (1994) defines a "formulary" as "a book listing medicinal substances and formulas."

That said, the amended Florida law obviously represents an attempt by the Florida legislature to conform a "preferred drug formulary" to at least *some* of the requirements of a

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[2] The Report and Recommendation of the federal magistrate judge, which was subsequently adopted by the district court, makes the following rather succinct observation:

> The Florida statutes use the phases "preferred drug formulary" and "preferred drug list" interchangeably. *E.g.*, Fla. Stat. § 409.91195(1), (4), (6), (7), (8), (9), (11). Sometimes the first phrase is used (subsections (1), (5), and (6)), sometimes the second is used (subsections (7) and (8)), and sometimes both are used interchangeably in the same subsection (subsections (4) and (9)). Thus, while it would appear that the law intends a "preferred drug list" to be a "formulary," it would appear equally true that the Florida Statutes intend any "formulary" to be a "preferred drug list." Since the words are used so interchangeably, little can be inferred from the choice of words.

Pharmaceutical Research & Mfr. of Am. v. Meadows, 184 F. Supp. 2d 1186, 1195 (N.D. Fla. 2001) (footnote omitted).

"formulary" as defined by the federal Medicaid statutes. For example, the first sentence of Fla. Stat. § 409.91195 reads as follows: "There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration for the purpose of developing a preferred drug formulary pursuant to 42 U.S.C. § 1396r-8." Paragraph (1) of this statute then defines the composition of the Medicaid Pharmaceutical and Therapeutics Committee in a way that is entirely consistent with a committee intended to develop a formulary within the meaning of § 1396r-8(d)(4). *Compare* § 1396r-8(d)(4)(A) ("The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State . . . ."), *with* Fla. Stat. § 409.91195(1) ("The Medicaid Pharmaceutical and Therapeutics Committee [charged with the development of a preferred drug formulary] shall be comprised as specified in 42 U.S.C. § 1396r-8 and consist of 11 members appointed by the Governor. Four members shall be physicians, . . . five members shall be pharmacists . . . and one member shall be a consumer representative. . . . At least one of the members shall represent the interests of pharmaceutical manufacturers.").

However, in addition to parallels between the federal Medicaid statute and the new Florida law, there are also important distinctions. For example, under the federal statute, *clinical* factors are the only permissible criteria for excluding a drug from the formulary. In contrast, the Florida law explicitly permits the Medicaid Pharmaceutical and Therapeutics Committee to consider *economic* factors when establishing the preferred drug list. *Compare* § 1396r-8(d)(4)(C) ("A covered outpatient drug may be excluded . . . only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and

there is a written explanation (available to the public) of the basis for the exclusion."), *with* Fla. Stat. § 409.91195(9) ("The Medicaid Pharmaceutical and Therapeutics Committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and *cost-effectiveness* of a product." (emphasis added)), and Fla. Stat. § 409.91195(4) ("To the extent feasible, the committee shall review all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the formulary, such that the formulary provides for medically appropriate drug therapies for Medicaid patients which achieve *cost savings* contained in the General Appropriations Act." (emphasis added)). The Florida law, in contrast to § 1396r-8(d)(4)(C), also does not contain any requirement that the Medicaid Pharmaceutical and Therapeutics Committee provide a written public explanation for its decision to exclude a particular drug from its preferred drug list.[3]

Differences between the Florida law and the federal Medicaid statute eventually became the topic of correspondence between Florida and federal administrators. On June 19, 2001, approximately three weeks after the Florida governor signed the 2001 amendments into law, AHCA submitted for approval the proposed revisions of Florida's Medicaid plan to the Center for Medicare & Medicaid Services

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[3] Note that the exclusion of a drug from the preferred drug list under the Florida law makes that drug subject to the prior authorization requirement. However, that same drug is *not* excluded from Medicaid coverage, which is the specific consequence of non-inclusion in a Medicaid formulary under § 1396r-8(d)(1)(B), (d)(4).

(CMS).[4] In an e-mail dated July 27, 2001, an official of the CMS informed the AHCA of various potential problem areas in the state's plan and made the following observation and suggestion:

> Under the section titled Prescribed Drug Formulary with Prior Authorization, the state's use of the word "formulary" doesn't meet the definition of formulary in Section 1927 of the Act. Therefore, the state should strike all references to "formulary" from their state plan and replace them with another term/phrase such as "preferred drug list."

Sharpe Supplemental Affidavit, Doc. 33, Exh. C., at 1-2. On August 8, 2001, AHCA Deputy Secretary Bob Sharpe sent a letter to the CMS that specifically addressed the state plan's ambiguous terminology:

> AHCA is unclear as to CMS's rationale for the statement that Florida's use of the term "formulary" doesn't meet the definition of the term used in Section 1927 [codified at 42 U.S.C. § 1396r-8], and as to the legal effect of using another term.

• • •

> If the Section 1927 use of "formulary" means a restrictive list designed to limit Medicaid coverage (i.e., to exclude certain drugs from coverage by the Medicaid program), then CMS is correct: the Florida

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[4] The CMS is the federal agency within the U.S. Department of Health & Human Services that oversees state Medicaid plans.

> "formulary" does not meet the definition of formulary in Section 1927. *The Florida formulary does not affect Medicaid coverage;* it merely establishes a preference for certain drugs, and submits all others (which remain covered services) to a prior authorization program.

Id., Exh. D., at 2 (emphasis added).

On September 14, 2001, Deputy Secretary Sharpe submitted to the CMS proposed revisions to the State's Medicaid Plan, including deletion of the phrase "preferred drug formulary," replacing it with "preferred drug list."[5] The new sentence reads, "In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. § 1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list." Four days latter, the

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[5] Contrary to suggestions made by the PhRMA, the AHCA's current position on the structure and mechanics of the Florida law is consistent with its pre-litigation stance. In a public meeting held on May 31, 2001, the same day the Governor's signed the bill into law, George Kitchens, R.Ph., Bureau Chief, AHCA Medicaid Pharmaceutical Services, made the following remark to clarify the effect of the prior authorization provision: "The physician has the overriding ability to say, 'This is the therapy I want and this is the one I'm going to continue to use,' and it will be approved that way. [The prior authorization requirement is] more or less making the physicians aware that there are some options and have you considered [sic] this." AHCA Pharmaceutical Manufacturers Formulary & Supplemental Rebate Briefing, May 31, 2001 transcript, at 68. Kitchens made a similar statement during a public meeting of the Medicaid Pharmaceutical and Therapeutics Committee. P&T Committee meeting, June 26, 2001 transcript, at 37-38.

CMS sent the AHCA a letter stating that Florida's Medicaid plan was now approved, retroactive to July 1, 2001, the day the 2001 amendments went into effect.

Notwithstanding ambiguities in the language of the Florida law, it is clear that the intended purpose of the preferred drug list is to reduce or offset the state's Medicaid expenditures. Under Fla. Stat. § 409.912(37), which is the other provision amended by the new Florida law, the establishment of the "preferred drug list" is directly tied to a "supplemental rebate" program. In most cases, the supplemental rebate is required to be at least 10 percent of the average manufacturer price over and above the § 1396r-8(a) federally mandated rebate. However, the statute provides a definite benefit to drug manufacturers: "Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug formulary." Fla. Stat. § 409.912(37)(a)7. Although some drugs, presumably because of product-specific clinical advantages, may make it onto the preferred drug list without agreeing to a supplemental rebate, other drugs make it onto the preferred list by providing comparable therapeutic benefits at a cost-effective price.[6] As noted, the preferred drug list in combination with the prior authorization provision has had a significant effect on the market

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[6] The statute reads in relevant part: "Agency decisions [on the preferred drug list] will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates." Fla. Stat. § 409.912(37)(a)7.

share of various drug products among Florida's Medicaid population.[7]

C.

On August 7, 2001, the PhRMA filed this lawsuit. The PhRMA contended that Florida's "preferred drug formulary" was a "formulary" within the contemplation of federal law, but that the demands of the Florida law fell short of the narrow requirements set forth in 42 U.S.C. § 1396r-8(d)(4). Specifically, the PhRMA argued that the AHCA impermissibly relied on economic rather than clinical criteria when developing its preferred drug list. The case was assigned to a magistrate judge, and on September 20, 2001, he issued a report and recommendation, which concluded that the Florida law had created a "prior authorization program" pursuant to § 1396r-8(d)(1)(A), (d)(5). On December 28, 2001, the district court adopted the magistrate judge's report and recommendations in full and granted summary judgment to the AHCA. The PhRMA now appeals.

II.

The central issue in this case is whether the Florida's system for covering Medicaid-eligible outpatient drugs conflicts in part with the governing federal statute, 42 U.S.C. § 1396r-8, and is therefore preempted under the Supremacy Clause, U.S. Const., art. VI, cl. 2. The Supreme Court has

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[7] The PhRMA cites the AHCA's own statistics as evidence of this trend. For example, following the enactment of the Florida law, the market share for the antimigrane drug Imitrex fell from 60 to 6 percent. The market share of the proton pump inhibitor drug Prilosec fell from 38 percent to 4 percent, while the market share of Prevacid, which was included on the preferred drug list, increased from 43 to 65 percent. The PhRMA cites other equally large market shifts among various prescription drugs.

held that preemption may be differentiated into three discrete categories: (1) express preemption, where a federal statute contains "explicit preemptive language"; (2) field preemption, in which the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it"; and (3) implied conflict preemption, in which "compliance with both federal and state regulations is a physical impossibility" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade v. National Solid Wastes Mgmt.*, 505 U.S. 88, 98, 112 S. Ct. 2374, 120 L. Ed. 2d 73 (1992) (quotations and citations omitted); *accord This That and the Other Gift & Tobacco, Inc. v. Cobb County*, 285 F.3d 1319, 1322 (11th Cir. 2002); *Boyes v. Shell Oil Prods. Co.*, 199 F.3d 1260, 1267 (11th Cir. 2000).

Medicaid is a cooperative state-federal program, in which each participating state designs and implements its own Medicaid program subject to certain strictures established by federal law. 42 U.S.C. § 1396a (prescribing general requirements of state Medicaid plan); *cf. Harris v. McRae*, 448 U.S. 297, 309, 100 S. Ct. 2671, 65 L. Ed. 2d 784 (1980) (referring to the Medicaid program as a "system of 'cooperative federalism'" (quoting *King v. Smith*, 392 U.S. 309, 316, 88 S. Ct. 2128, 20 L. Ed. 2d 1118 (1968)). As such, we readily conclude that the categories of express preemption and implied preemption are inapplicable here. Under § 1396r-8(d), the states are clearly given the authority to impose certain restrictions on the coverage of outpatient drugs, including a formulary for excluding coverage of certain outpatient drugs, or a distinct prior authorization program. Similarly, the federal government cannot "occupy the field" when no Medicaid relief is available unless a state designs and implements its own Medicaid program. Therefore, implied conflict preemption is the only category left standing and will be analyzed here.

In this circuit, a state statute is generally not entitled to a presumption against implied conflict preemption. *See Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) ("When considering implied preemption, no presumption exists against preemption."); *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997) (in a case involving implied conflict preemption under the Federal Boat Safety Act, noting that "we do not apply a presumption against preemption, even though common law tort claims are a mechanism of the police powers of the state"). However, Medicaid is one of several cooperative state-federal program covered by the Social Security Act, and the Supreme Court has suggested that preemption for these types of programs may be difficult to establish. In *New York State Department of Social Services v. Dublino*, 413 U.S. 405, 93 S. Ct. 2507, 37 L. Ed. 2d 688 (1973), the Court addressed whether a New York welfare reform statute preempted another provision of the Social Security Act. In upholding the New York law, the Supreme Court observed, "Where coordinate state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one." *Id.* at 421 (reviewing possible preemption under the Federal Work Incentive Program); *accord Concannon*, 249 F.3d at 75; *New Mexico Dep't of Human Servs. v. Department of Health & Human Servs. Health Care Financing Admin.*, 4 F.3d 882, 886 (10th Cir. 1993); *Wash. Dep't of Soc. & Health Servs. v. Bowen*, 815 F.2d 549, 557 (9th Cir. 1987). We therefore believe there may be a presumption against preemption here.

Bearing this presumption in mind, we turn to the preemption analysis. Implied conflict preemption occurs when (a) compliance with both federal and state regulations is a physical impossibility, or (b) when a state law is an obstacle to execution and accomplishment of the objectives and purpose of a Congressional enactment. *See Gade*, 505 U.S. at

98; *This That and the Other Gift & Tobacco*, 285 F.3d at 1322; *Boyes*, 199 F.3d at 1267. If the Florida law created a *Medicaid* "formulary," we would agree with the PhRMA that Florida officials developing the preferred drug list could not consider a drug's "cost-effectiveness," as required under Fla. Stat. § 409.91195(9), when the governing federal statute clearly limits such decisions to clinical issues of safety and drug effectiveness. *See* § 1396r-8(d)(4)(C).

However, we need not belabor the issue of physical impossibility because we agree with the magistrate judge and the district court that a reasonable reading of the Florida law suggests that the state has created a "prior authorization program" within the meaning of § 1396r-8(d)(1)(A), (d)(5). Subsection (d)(1)(A) permits a state Medicaid plan to "subject to prior authorization *any* covered outpatient drug." (emphasis added). Further, the text of the Medicaid statute contains only two specific limitations on prior authorization: a response within 24 hours and the availability of an emergency 72 hour supply of the drug. *Cf. Concannon*, 249 F.3d at 76 (stating that the only two requirements for a prior authorization program under § 1396r-8(d)(5) are "the 24-hour response and the 72-hour drug-supply requirements"). Because the Florida law satisfies both of these requirements, *see* Fla. Stat. § 409.912(37)(a)1, compliance with both federal and state law is certainly possible.

Our determination that the Florida law creates only a prior authorization program, and not a "formulary" in the federal sense, is further buttressed by substantial record evidence that the State's preferred drug list does not actually "exclude" any Medicaid-eligible outpatient drug from coverage.[8] Under the federal Medicaid statute, exclusion of a

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[8] The issue of exclusion is an important one. *PhRMA v. Concannon*, *supra*, is the only case that has addressed the legal con-
(continued...)

tours of a Medicaid prior authorization program, and it is currently pending before the Supreme Court. In *Concannon*, the First Circuit held that a similar supplemental rebate program under Maine law satisfied the requirements of a prior authorization program under § 1396r-8(d)(1)(A), (d)(5). However, the disputed Maine law actually has a greater potential for interfering with a prescribing doctor's medical judgment. In *Concannon*, Maine acknowledged "that it will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant, but [the state] insists that the Medicaid recipient will always receive medically necessary drugs." 249 F.3d at 77. Recognizing the possibility that a prescribing doctor's first choice medication may not be covered, the First Circuit specified that its ruling was limited to a facial attack on the Maine law: "This decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirement as 'as applied.'" *Id.* at 78.

Under the Florida law, the prescribing physician retains the final authority to prescribe a Medicaid-eligible outpatient drug. *See* note 5, *supra*. On the record before us, we have no reason to believe that a prescribing physician would compromise the medical care of his patient in order to avoid making a telephone call to obtain a 12-month authorization of a medication not on the preferred drug list. From July 1, 2001 to September 30, 2001, the AHCA agent pharmacist received 6,565 requests for non-preferred drugs; 2,874 prescriptions were authorized and 3,691 resulted in the physician's changing the prescription to a drug on the preferred list. These statistics suggest that in over 55 percent of these cases, the prescribing physicians received additional information from the AHCA pharmacist that persuaded them that a drug on the preferred list was medically appropriate. In short, it appears that the Florida law permits a clinical dialogue between a (continued...)

drug from a "formulary" has the effect of actually denying coverage of, or payment for, certain Medicaid-eligible drugs. As the PhRMA correctly points out, a decision to remove a drug from a § 1396r-8(d)(4) formulary must be based solely on clinical factors. Because the statutory requirements of such a formulary also mandate a prior authorization program, *see* § 1396r-8(d)(4)(D) (specifying as one of the requirements of a formulary is that "[t]he State plan permits coverage [of an excluded drug] . . . pursuant to a prior authorization program that is consistent with paragraph (5)"), we construe this requirement to mean that a state must *consider* coverage for an excluded drug on a case-by-case basis. The decision to provide coverage would presumably be based on medical information conveyed by the prescribing doctor to the state agency that administers the Medicaid program.[9] However, the AHCA maintains that

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doctor and a pharmacist that can reduce the state's Medicaid costs without jeopardizing patient care.

[9] Based on our interpretation of § 1396r-8, we note that the prior authorization requirement of a federal Medicaid formulary, pursuant to subsection (d)(4)(D), is likely to serve a different function than a prior authorization program authorized under subsections (d)(1)(A), (d)(5). Since a federal formulary *excludes* from coverage Medicaid-eligible outpatient drugs, *see* subsection (d)(1)(B)(iv), the prior authorization provision specified by subsection (d)(4)(D) permits the prescribing doctor to obtain an exception to this exclusion, presumably because of medical factors specific to his or her patient. In contrast, a prior authorization program under subsections (d)(1)(A), (d)(5), such as that provided in the Florida law, can be used to inform doctors about the availability of drugs with comparable therapeutic properties that are also more cost-effective for the state. Presumably, some doctors will learn to avoid the prior authorization program by routinely looking for a suitable drug on the "preferred drug list," Fla. Stat. (continued...)

the Florida law actually creates a prior authorization program that covers all Medicaid-eligible drugs, provided that the prescribing doctor contacts the state pharmacist. The AHCA has consistently advanced this interpretation since the enactment of the Florida law. *See* note 5, *supra*. As the state agency that administers the state Medicaid plan, and because its construction is reasonable, we believe that the AHCA's interpretation of the Florida law is entitled to substantial deference. *See Enterprise Leasing Co. v. Metropolitan Airports Comm.*, 250 F.3d 1215, 1223 (8th Cir. 2001) (holding that "substantial deference is afforded to a state agency's interpretation of a statute the agency administers" and that the agency's interpretation cannot be set aside "unless it is arbitrary, capricious, an abuse of discretion, or otherwise not supported by law"); *see also National RR Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 417, 112 S. Ct. 1394, 118 L. Ed. 2d 52 (1992) ("Judicial deference to reasonable interpretations by an agency of a statute that it administers is a dominant, well-settled principle of federal law.").

Turning to the second species of implied conflict preemption, we do not believe that the Florida law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade*, 505 U.S. at 98.

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§ 409.91195(4); hence, the shifts in market share following the enactment of the Florida law. *See* note 7, *supra*. Based on the record before us, it is clear that prescribing physicians retain the authority to override any suggestions made by the AHCA state pharmacist. However, if the Florida law had actually created a federal formulary, and complied with all the requirements of subsection (d)(4), it would be permissible for the state to retain the final authority over coverage of, or payment for, non-formulary drugs.

As noted by the First Circuit in *Concannon*, the "primary purpose of Medicaid is to enable states to provide medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services.'" 249 F.3d at 75 (quoting 42 U.S.C. § 1396 (2000)). In this case, the Florida law operates to drive down the cost of prescription drugs under the Medicaid program by providing drug manufacturers with a strong economic incentive to offer the state a supplemental rebate. Moreover, these rebates do not necessarily have to be cash adjustments that can be applied to other, unrelated general fund expenditures. Rather, the supplemental rebates can directly improve the coverage and efficiency of the state Medicaid program by being applied to "disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program in the same year the rebate reduction is included in the General Appropriations Act." Fla. Stat. § 409.912(37)(a)7. By stretching its Medicaid dollars, the Florida law has the potential for providing more and better medical services to the target population. Finally, because Florida's preferred drug list is based on *both* clinical and cost-related factors, *see* Fla. Stat. § 409.91195(9) (requiring that preferred drug list recommendations be based on "clinical efficacy, safety, and cost-effectiveness of a product"), the Florida law leaves open the possibility that a medically superior drug will be included on the list even without a supplemental rebate.

In its effort to demonstrate that the Florida law frustrates the objectives of the federal Medicaid legislation, the PhRMA contends that the state of Florida has created a "de facto" formulary that sidesteps the clinical safeguard requirements of § 1396r-8(d)(4). The PhRMA constructs its rather complex argument by discussing a series of revisions to the prescription drug provisions of the Social Security

Act. The PhRMA's contentions can be summarized in the following manner.

In 1990, Congress banned Medicaid formularies because states were using them to eliminate coverage for expensive but medically necessary drugs. *See* Pub. L. No. 101-508, § 4401(a)(2)(C), 104 Stat. 1388-143 (1990) (amending 42 U.S.C. § 1396a(a)(54)). According to the legislative debate cited by the PhRMA, the then predominant patterns of using formularies had been compromising the quality of medical care for Medicaid patients, and the formularies were therefore eliminated by Congress. In 1993, Congress enacted the current version of § 1396r-8(d). *See* Pub. L. No. 103-66, § 13602(a), 107 Stat. 616-17 (1993) (amending 42 U.S.C. § 1396r-8 and adding the current subsection (d)(4)). Although the new law once again permitted the creation and use of formularies, it included stringent clinical safeguards to reduce the potential for abuse. However, as the PhRMA points out, the prior authorization provision survived all of these changes (i.e., it was part of the pre-1990 law and remained largely unchanged by the 1990 and 1993 amendments), thus giving rise to the inference (according to the PhRMA) that Congress never intended that a prior authorization program under this provision would be used to impose significant restrictions on prescribing doctors. Therefore, because the present Florida law, deemed to authorize a "prior authorization program," essentially replicates the abuses that crept in under the pre-1990 formularies (or so the PhRMA alleges), the PhRMA contends that the Florida law cannot be squared with the Congressional intent motivating the 1990 and 1993 reforms. To support its theory, the

PhRMA refers us to copious volumes of legislative history.[10]

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[10] To make its case, the PhRMA has assiduously plumbed the sprawling legislative history of the Medicaid prescription drug statute. For example, the PhRMA directs our attention to a 1990 Senate hearing on proposed changes to the Medicaid prescription drug provisions, in which Representatives Wyden and Cooper testified that approximately 20 states had established formularies that restricted, primarily on the basis of cost, the number of covered outpatient drugs available to Medicaid patients. *See Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 Before the Subcomm. on Health for Families and the Uninsured of the Comm. on Finance*, S. HRG. 101-1261, 101st CONG. 10, 19 (1990). Although these debates contained some reference to existing flaws in the prior authorization programs, *see id.* at 17 (statement by Rep. Wyden that "under the status quo there are prior authorization programs where no one even answers the phone"), the PhRMA maintains that these debates suggest that the problems with prior authorization programs were relatively minor compared to the widespread abuse of the formulary provisions — hence the scope of the 1990 amendments, which preserved the former but eliminated the latter.

Three years later, the tenor of congressional discourse had apparently changed. As an example of what motivated the 1993 amendments to the Medicaid prescription drug statute, the PhRMA invites our attention to a statement made by William Toby, Jr., Acting Administrator of the Health Care Finance Administration, requesting that states once again be permitted to establish formularies in order that they might have "greater flexibility to ensure the effective use of Medicaid funds." *Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce*, H. HRG. 103-61, 103rd CONG. 7 (1993). Once again relying on legislative debates, the PhRMA argues that the 1993 amendments were carefully designed to preserve the patient ac-

(continued...)

The primary flaw in the PhRMA's analysis is that the statutory interpretation problem here arises from an ambiguity in the Florida law, *not* in the federal Medicaid statute. The text of § 1396r-8(d) clearly authorizes: (1) a "prior authorization program," which requires as a *condition* of Medicaid coverage or payment, that the relevant state agency be contacted prior to the dispensing of *any* covered outpatient drug; and (2) a "formulary," which permits the more stringent consequence of excluding coverage or payment with respect to certain Medicaid-eligible drugs if certain *clinical* criteria are adhered to. But the last sentence of § 1396r-8(d)(4), which is the provision that specifies the minimum requirements for a formulary, also contains the following unequivocal proviso: "A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph." As we have observed on many previous occasions, when an enactment of Congress has spoken with this level of clarity, recourse to legislative history is unnecessary. *See Federal Reserve Bank of Atlanta v. Thomas*, 220 F.3d 1235, 1239 (11th Cir. 2000) (stating that statutory language must be ambiguous before "courts may examine extrinsic materials, including legislative history, to determine Congressional

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cess to drugs that was achieved through the 1990 amendments. *See id.* at 453 (quoting Rep. Waxman that the 1990 amendment represented a "government-industry compact" that expanded the availability of Medicaid of drugs while simultaneously extracting rebates from manufacturers). As a result, the post-1993 incarnation of the Medicaid formulary is subject to the strict clinical safeguards of § 1396r-8(d)(4).

The PhRMA contends that the Florida law upsets this carefully calibrated equilibrium. However, we decline the PhRMA's invitation to scour the legislative history in order to improve upon a clearly drafted federal statute.

intent"); *United States v. Orozco*, 160 F.3d 1309, 1313 (11th Cir. 1998) ("Review of the legislative history is not necessary unless a statute is inescapably ambiguous'" (quotations omitted)); *United States v. Veal*, 153 F.3d 1233, 1245 (11th Cir. 1998) (same); *see also United States v. Rush*, 874 F.2d 1513, 1514 (11th Cir. 1989) (stating that legislative history cannot be relied upon to create an ambiguity when the statutory text is clear).

The PhRMA further argues that Congress intended the prior authorization provision of § 1396r-8(d)(5) to serve as an "adjunct" to the requirements of a formulary under § 1396r-8(d)(4). However, this construction of the Medicaid statute by the PhRMA renders meaningless the proviso in subsection (d)(4) that a "prior authorization program established . . . under paragraph (5) is not a formulary subject to the requirements of [paragraph (4)]." The PhRMA's interpretation also cannot be reconciled with the unequivocal language contained elsewhere in the statute: "A State may subject to prior authorization *any* covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." § 1396r-8(d)(1)(A) (emphasis added).

The PhRMA attempts to dodge these inconsistencies by arguing that "the precise contours of a state's prior authorization powers under [paragraph (5)] are not at issue in this case" and that, notwithstanding these ambiguities, the Florida law undermines the explicit clinical safeguard requirements of a § 1396r-8(d)(4) formulary. This line of reasoning is unconvincing. The Florida law does not *exclude* coverage for any Medicaid eligible drugs, which is the literal effect of a § 1396r-8(d)(4) formulary. *See* § 1396r-8(d)(1)(B)(iv) (permitting a State to "*exclude* or otherwise restrict coverage of a covered outpatient drug if . . . the State has *excluded coverage* of the drug from its formulary established in accordance with paragraph (4)" (emphasis added)). Instead, the Florida law merely *conditions* coverage for non-

preferred drugs on whether the prescribing physician has followed the prior authorization procedure.

If this case presents us with difficult issues of statutory interpretation, this difficulty arises from the confusing phraseology of the Florida law. Section 409.91195 begins with the sentence, "There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration [AHCA] for the purpose of developing a *preferred drug formulary* pursuant to 42 U.S.C. § 1936r-8." (emphasis added). However, the term "preferred drug formulary" does not appear in the governing Medicaid statute, and the reference to § 1396r-8 resolves nothing; a prior authorization program is defined in subsections (d)(1)(A) and (d)(5), while a "formulary" is defined in subsections (d)(1)(B) and (d)(4). Further, section 409.91195 of the Florida law uses the term "preferred drug formulary" interchangeably with "preferred drug list": subsections (1) and (6) refer to "preferred drug formulary"; subsections (7) and (8) refer to "preferred drug list"; and subsections (4) and (9) refer to "formulary" and "preferred drug list" as if they were synonyms. As noted in the report and recommendation submitted by the magistrate judge, "while it would appear that the law intends a 'preferred drug list' to be a 'formulary,' it would appear equally true that the Florida Statutes intend any 'formulary' to be a 'preferred drug list.' Since the words are used so interchangeably, little can be inferred from the choice of words."

The PhRMA contends that the use of the word "formulary" effectively eliminates any resulting ambiguity and requires anything designated as a "formulary" to be subject to the clinical safeguards of § 1396r-8(d)(4). However, this argument is unpersuasive. As previously noted, "formulary" is not a term of art that is exclusive to federal Medicaid law. The dictionary definition of "formulary" is a "book listing medicinal substances and formulas." Webster's New Collegiate Dictionary (1994). The PhRMA also argues that the

Florida legislature intended to create a § 1396r-8(d)(4) formulary because it mandated a committee of physicians and pharmacists that satisfied the specific requirements of subsection (d)(4)(A). Yet, if the Florida legislature were carefully conforming the Florida statutes to the requirements of the governing Medicaid statute, it is puzzling that it failed to include a provision for a "written explanation (available to the public)" of a decision to exclude a particular drug from the formulary, as required by § 1396r-8(d)(4)(C). The AHCA insists that the Florida law permits the state to implement a conforming Medicaid formulary at a later date, and that the Medicaid Pharmaceutical and Therapeutics Committee, created pursuant to section 409.91195, would already be in place to assume this additional duty. As the agency charged with administering the Florida law, we must defer to its reasonable construction of an ambiguous state statute. *See Enterprise Leasing Co.*, 250 F.3d at 1223 (according substantial deference to state agency charged with the administration of a statute when its construction is reasonable).

III.

In summary, we hold that the 2001 amendments to the Florida law provide for a prior authorization program within the meaning of 42 U.S.C. § 1396r-8(d)(1)(A), (d)(5). The AHCA has adopted a reasonable construction of the Florida law that comports with the requirements of the governing federal Medicaid statute. The judgment of the district court is therefore AFFIRMED.

Appendix

The following is the text of Fla. Stat. § 409.91195:

> There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration for the purpose of de-

veloping a preferred drug formulary pursuant to 42 U.S.C. s. 1396r-8.

(1) The Medicaid Pharmaceutical and Therapeutics Committee shall be comprised as specified in 42 U.S.C. s. 1396r-8 and consist of 11 members appointed by the Governor. Four members shall be physicians, licensed under chapter 458; one member licensed under chapter 459; five members shall be pharmacists licensed under chapter 465; and one member shall be a consumer representative. The members shall be appointed to serve for terms of 2 years from the date of their appointment. Members may be appointed to more than one term. The Agency for Health Care Administration shall serve as staff for the committee and assist them with all ministerial duties. The Governor shall ensure that at least some of the members of the Medicaid Pharmaceutical and Therapeutics Committee represent Medicaid participating physicians and pharmacies serving all segments and diversity of the Medicaid population, and have experience in either developing or practicing under a preferred drug formulary. At least one of the members shall represent the interests of pharmaceutical manufacturers.

(2) Committee members shall select a chairperson and a vice chairperson each year from the committee membership.

(3) The committee shall meet at least quarterly and may meet at other times at the discretion of the chairperson and members. The committee shall comply with rules adopted by the agency, including notice of any meeting of the committee pursuant to the requirements of the Administrative Procedure Act.

(4) Upon recommendation of the Medicaid Pharmaceutical and Therapeutics Committee, the agency shall adopt a preferred drug list. To the extent feasible, the committee shall review all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the formulary, such that the formulary provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

(5) Except for mental health-related drugs, antiretroviral drugs, and drugs for nursing home residents and other institutional residents, reimbursement of drugs not included in the formulary is subject to prior authorization.

(6) The Agency for Health Care Administration shall publish and disseminate the preferred drug formulary to all Medicaid providers in the state.

(7) The committee shall ensure that interested parties, including pharmaceutical manufacturers agreeing to provide a supplemental rebate as outlined in this chapter, have an opportunity to present public testimony to the committee with information or evidence supporting inclusion of a product on the preferred drug list. Such public testimony shall occur prior to any recommendations made by the committee for inclusion or exclusion from the preferred drug list. Upon timely notice, the agency shall ensure that any drug that has been approved or had any of its particular uses approved by the United States Food and Drug Administration under a priority review classification will be reviewed by the Medicaid Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting. To the extent possible, upon notice by a manufacturer the agency shall

also schedule a product review for any new product at the next regularly scheduled Medicaid Pharmaceutical and Therapeutics Committee.

(8) Until the Medicaid Pharmaceutical and Therapeutics Committee is appointed and a preferred drug list adopted by the agency, the agency shall use the existing voluntary preferred drug list adopted pursuant to s. 72, chapter 2000-367, Laws of Florida. Drugs not listed on the voluntary preferred drug list will require prior authorization by the agency or its contractor.

(9) The Medicaid Pharmaceutical and Therapeutics Committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and cost-effectiveness of a product. When the preferred drug formulary is adopted by the agency, if a product on the formulary is one of the first four brand-name drugs used by a recipient in a month the drug shall not require prior authorization.

(10) The Medicaid Pharmaceutical and Therapeutics Committee may also make recommendations to the agency regarding the prior authorization of any prescribed drug covered by Medicaid.

(11) Medicaid recipients may appeal agency preferred drug formulary decisions using the Medicaid fair hearing process administered by the Department of Children and Family Services.

The following is the text of Fla. Stat. § 409.912(37):

(37)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. Medicaid prescribed-drug coverage for brand-name drugs for adult Medicaid recipients is limited

to the dispensing of four brand-name drugs per month per recipient. Children are exempt from this restriction. Antiretroviral agents are excluded from this limitation. No requirements for prior authorization or other restrictions on medications used to treat mental illnesses such as schizophrenia, severe depression, or bipolar disorder may be imposed on Medicaid recipients. Medications that will be available without restriction for persons with mental illnesses include atypical antipsychotic medications, conventional antipsychotic medications, selective serotonin reuptake inhibitors, and other medications used for the treatment of serious mental illnesses. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply. The agency shall continue to provide unlimited generic drugs, contraceptive drugs and items, and diabetic supplies. Although a drug may be included on the preferred drug formulary, it would not be exempt from the four-brand limit. The agency may authorize exceptions to the brand-name-drug restriction based upon the treatment needs of the patients, only when such exceptions are based on prior consultation provided by the agency or an agency contractor, but the agency must establish procedures to ensure that:

a. There will be a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation;

b. A 72-hour supply of the drug prescribed will be provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.; and

c. Except for the exception for nursing home residents and other institutionalized adults and except for drugs on the restricted formulary for which prior authorization may be sought by an institutional or community pharmacy, prior authorization for an exception to the brand-name-drug restriction is sought by the prescriber and not by the pharmacy. When prior authorization is granted for a patient in an institutional setting beyond the brand-name-drug restriction, such approval is authorized for 12 months and monthly prior authorization is not required for that patient.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the average wholesale price less 13.25 percent.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The

agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease-management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-participating providers.

5. The agency shall develop and implement a program that requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by Medicaid-participating prescribers or prescribers who write prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug formulary in accordance with 42 U.S.C. s. 1396r-8, and, pursuant to the establishment of such formulary, it is

authorized to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 10 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 25 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug formulary. However, a pharmaceutical manufacturer is not guaranteed placement on the formulary by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency is authorized to contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term " supplemental rebates" may include, at the agency's discretion, cash rebates and other program benefits that offset a Medicaid expenditure. Such other program benefits may include, but are not limited to, disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program in the same year the rebate reduction is included in the General Appropriations Act. The

agency is authorized to seek any federal waivers to implement this initiative.

8. The agency shall establish an advisory committee for the purposes of studying the feasibility of using a restricted drug formulary for nursing home residents and other institutionalized adults. The committee shall be comprised of seven members appointed by the Secretary of Health Care Administration. The committee members shall include two physicians licensed under chapter 458 or chapter 459; three pharmacists licensed under chapter 465 and appointed from a list of recommendations provided by the Florida Long-Term Care Pharmacy Alliance; and two pharmacists licensed under chapter 465.

9. The Agency for Health Care Administration shall expand home delivery of pharmacy products. To assist Medicaid patients in securing their prescriptions and reduce program costs, the agency shall expand its current mail-order pharmacy diabetes-supply program to include all generic and brand-name drugs used by Medicaid patients with diabetes. Medicaid recipients in the current program may obtain nondiabetes drugs on a voluntary basis. This initiative is limited to the geographic area covered by the current contract. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

(b) The agency shall implement this subsection to the extent that funds are appropriated to administer the Medicaid prescribed-drug spending-control program. The agency may contract all or any part of this program to private organizations.

(c) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed-drug expenditures.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA,
TALLAHASSEE DIVISION

No. 4:01cv356-WS

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,
Plaintiff,

v.

RHONDA M. MEDOWS, in her official capacity as Secretary of the Agency for Health Care Administration of the State of Florida, and BOB SHARPE, in his official capacity as Deputy Secretary of Medicaid, Agency for Health Care Administration of the State of Florida,
Defendants.

Before
Stafford, *Senior United States District Judge*

ORDER
Entered: December 28, 2001

Robert Wayne Pass, Carlton Fields Ward Etc., Martha Harrell Chumbler, Carlton Fields, Tallahassee, FL, *David H. Remes, Steven J. Rosenbaum,* Covington & Burling, Washington, DC, for Plaintiff.

Gary J. Anton, Stowell Anton & Kraemer, *William H. Roberts, Steven Alfons Grigas, L. William Porter*, Tallahassee, FL, for Defendants.

Order Directing Entry of Judgment in Defendants' Favor

Before the court is the magistrate judge's report and recommendation (doc. 34) docketed September 20, 2001. The magistrate judge recommends that the plaintiff's motion (doc. 7) for preliminary injunction be denied. The plaintiff has filed objections (doc. 43) to the report and recommendation, and the defendants have filed a response (doc. 46) to the plaintiff's objections. This court has reviewed the entire record, including the transcript of proceedings before the magistrate judge. For the reasons stated by the magistrate judge, this court adopts the magistrate judge's report and recommendation.

Also before the court are the parties' cross-motions (docs. 21 & 40) for summary judgment. The parties have been advised (doc. 48) that the motions would be taken under advisement as of a date certain. Because the motion for preliminary injunction and the cross-motions for summary judgment raise largely identical issues, the parties have suggested that concurrent resolution of the motions would be appropriate, indeed helpful. Again for the reasons stated by the magistrate judge, this court concludes that the plaintiff's motion for summary judgment and permanent injunctive relief must be denied.

The plaintiff asks this court to enjoin enforcement of two recently amended Florida laws: sections 409.91195 and 409.912(37) of the Florida Statutes. According to the plaintiff, these laws authorize the creation of a state Medicaid formulary in violation of subsection (d)(4) of section 1927 of the Social Security Act (the "federal Medicaid law"). The magistrate judge determined—and this court agrees—that sections 409.91195 and 409.912(37)(a), as amended in

2001, do not authorize the creation of a "formulary" as that term is used in the federal Medicaid law but, instead, allow the establishment of a "preferred drug list" and a "prior authorization program" expressly permitted by the federal Medicaid law. 42 U.S.C. § 1396r-8(d)(1)(A), (d)(4) & (d)(5). The plaintiff's arguments to the contrary are not persuasive.

Because the plaintiff has failed to demonstrate a conflict between the challenged Florida statutes and the federal Medicaid law, it is ORDERED:

1. The magistrate judge's report and recommendation is ADOPTED and incorporated by reference into this order.

2. The plaintiff's unopposed motion (doc. 47) for simultaneous oral argument is DENIED.

3. The plaintiff's motion (doc. 7) for preliminary injunction is DENIED.

4. The plaintiff's cross-motion (doc. 40) for summary judgment and permanent injunctive relief is DENIED.

5. The defendants' motion (doc. 21) to dismiss or, in the alternative, for summary judgment is GRANTED.

6. The clerk is directed to enter judgment in the defendants' favor.

REPORT AND RECOMMENDATION

SHERRILL, United States Magistrate Judge:

Plaintiff has moved for a preliminary injunction. Doc. 7 (motion) and 8 (memorandum with attachments). Defendants have filed a response. Docs. 19 (memorandum) and 20 (affidavits). Plaintiff has filed a reply memorandum. Doc. 25. A hearing was held on September 20, 2001.

I. Summary of the issues

Plaintiff is an organization of major pharmaceutical companies. Plaintiff's members currently account for more than 75% of the brand-name prescription drug sales in the United States. Doc. 8, p. 5. Defendants are state officers charged with implementation of the Florida Medicaid program.

The Medicaid program enacted by Congress in 1965 is a joint venture by the United States and each State. The United States pays about 56% of the cost in Florida, and Florida pays the rest. *Id.*, p. 6. The Medicaid program directly reimburses pharmacists for drugs which they provide to Medicaid beneficiaries. *Id.*, p. 6, n. 4. The pharmaceutical manufacturers who are members of Plaintiff sell prescription drugs in Florida through the Medicaid program.

Drug manufacturers are required by federal Medicaid law to enter into agreements with either the United States or a State to sell their products through the Medicaid program. The discount is 15.1%, with limited exceptions. If the drug manufacturers do not agree to the discount, their drugs are not used for Medicaid beneficiaries.

The State of Florida has recently enacted a law which provides that drug manufacturers must agree to an additional 10% discount in order that their drugs be included on the preferred list of drugs in the Florida Medicaid program. To date, manufacturers have refused to enter such agreements such that over 50% of the total drugs in the program are not on the preferred list. This has resulted in the omission of 1,006 of drugs from Florida's preferred list of Medicaid drugs. All of these omitted drugs are on the federal list because the manufacturers have entered into agreements with the United States, agreeing to the 15.1% discount.

The drugs which have been excluded from the list may still be prescribed by physicians to Medicaid beneficiaries.

To do so, however, the physician must obtain prior approval for each prescription. Approval is automatic upon request. The approval procedure gives State officials a chance to advise the physician as to alternative drugs which are on the preferred list.

Plaintiff contends that it is the intent of Congress that the only drugs which a state may exclude from its Medicaid list are those which provide no significant, clinically meaningful therapeutic advantage. Plaintiff contends that Florida's law excludes drugs for which the manufacturer has not agreed to rebate the additional 10% and thus conflicts with the federal statute. As a consequence, Plaintiff contends that the Florida statute violates the Supremacy Clause.

II. The undisputed facts

Plaintiff conceded at oral argument that the material facts are not in dispute, and the question is primarily one of law. Federal Medicaid law provides: "In order for payment to be available under section 1396(a) of this title for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary [of the Department of Health and Human Services], on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer) . . . ." 42 U.S.C. § 1396r-8(a)(1). Doc. 8, p.7; Doc. 8, attachment B, is a copy of the federal statute.[1] The rebate is at

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[1] The memorandum, doc. 8, refers to the new Florida law, CS for CS for SB 72, as attachment A, and the federal statute, Social Security Act (SSA) § 1927 (42 U.S.C. § 1396r-8) as attachment B. These were not marked as such when filed, but the court has labeled them A and B. There are also other labeled attachments to doc. 8 in a separate folder in this file.

least 15.1% of the "average manufacturer price," and could be more if the differential between that price and the manufacturer's nationwide "best price" is greater. *Id.*, p. 8. .

In 1990, Congress abolished restrictive state Medicaid drug formularies. Doc. 8, p. 7 and n. 7. It appears undisputed also that it was Congressional intent to require drug manufacturers to give a 15.1% discount for drugs provided to state Medicaid programs and to require States which elected to cover prescription drugs in their Medicaid programs to "cover all products on which rebates are available." *Id.*, n. 8, quoting Representative Waxman in 1993.

In 1993, Congress again amended the statutes, allowing States to established their own formularies. As amended, 42 U.S.C. § 1396r-8(d)(4) establishes the rules for State formularies. Paragraph (d)(4) provides that a "State may establish a formulary if the formulary meets the following requirements." The requirements are that the formulary be "developed by a committee consisting of [persons] appointed by the Governor of the State," that "the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section [rebate agreements with the United States]," and that a drug may be excluded from the State formulary "only if" the drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome . . . ." § 1396r-8(d)(4)(A), (B), and (C). A fourth requirement for a state formulary is found in subparagraph (D) of paragraph (d)(4). That subparagraph provides that the State must permit a drug which has been "excluded from the formulary" to be covered "pursuant to a prior authorization program that is consistent with paragraph (5)."

Paragraph (d)(4) of the federal statute ends with this sentence: "A prior authorization program established by a State under paragraph (5) *is not a formulary subject to the re-*

quirements of this paragraph." (Emphasis added.) Subparagraph (5) then provides:

> (5) Requirements of prior authorization programs
>
> A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication . . . only if the system providing for such approval —
>
> (A) provides response by telephone or other telecommunication device with 24 hours of a request for prior authorization; and
>
> (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in any emergency situation (as defined by the Secretary).

42 U.S.C. § 1396r-8(d)(5)(A) and (B).

The Florida law which is challenged in this suit consists of sections 409.91195 and 409.912, Florida Statutes, as amended by Chapter 2001-104, Laws of Florida. The new law took effect on July 1, 2001. A copy of the enactment is attachment A to doc. 8.

Section 409.91195 has been amended to create a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration "for the purpose of

developing a preferred drug formulary pursuant to 42 U.S.C. § 1396r-8." *Id.*, § 8, amending FLA. STAT. § 409.91195. Upon recommendation of the Committee, the Agency is to "adopt a preferred drug list." *Id.*, amending FLA. STAT. § 409.91195(4). The agency is authorized to negotiate "supplemental rebates" from manufacturers of "no less than 10 percent of the average manufacturer price" but no greater than 25 percent when combined with the federal rebate. *Id.*, § 9, amending FLA. STAT. § 409.912(37)(a)7. The new law provides that: "Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the [Committee] will consider a product for inclusion on the preferred drug formulary." *Id.*

It is not disputed that Florida initially did not initially obtain approval of the Secretary of the Department of Health and Human Services before entering into these supplemental rebate agreements with manufacturers. Florida has argued that such approval is needed only if the State rebate agreements are in lieu of, rather supplemental to, the federal rebates. Doc. 20, affidavit of Bob Sharpe, ¶ 6. The Florida rebate program is supplemental according to Sharpe. *Id.* Attached to the affidavit of Sharpe is a letter from Charlene Brown, Deputy Director, Health Care Financing Administration, Department of Health and Human Services. Ms. Brown states that the Florida program "appears to describe a prior authorization program" rather than a "formulary" program. Ms. Brown also distinguishes between State rebates which are supplemental and those which supplant federal rebates.

Sharpe stated in his initial affidavit, however, that "a State plan amendment and a State supplemental rebate agreement have been submitted to CMS [Department of Health and Human Services] for approval." *Id.*, ¶ 6. On September 18, 2001, the Department of Health and Human Services approved Florida's program for obtaining supplemental rebates from drug manufacturers. It also approved the

plan for requiring prior authorization for drugs for which no supplemental rebate agreement exists. Doc. 33 and ex. 1 (supplemental affidavit of Sharpe), ¶ 6, and ex. F. The approval was retroactively effective *nunc pro tunc* July 1, 2001. *Id.*, ex. F, p. 5.

Except for mental health drugs, anti-retroviral drugs, and drugs for institutional residents, "reimbursement for drugs not included in the formulary is subject to prior authorization." *Id.*, amending FLA. STAT. § 409.91195(5). It is undisputed that Florida's "preferred drug list calls for the prior authorization of any drug that is not currently on the list." Doc. 19, p. 4.

Plaintiff contends that Florida will not place a drug on the preferred list if the manufacturer does not agree to the extra 10% rebate, unless the manufacturer's price is already at that level. Doc. 8, pp. 12-13, quoting Defendant Sharpe. Defendants disagree, citing the affidavit of George Kitchens: "Many drugs are on the Florida PDL [preferred drug list] even though the manufacturer has not entered into a supplemental rebate agreement with the State for these drugs." Doc. 20, affidavit of George Kitchens, ¶ 3. It is presumed that these are drugs for which the price is already at the 25% rebate level, but there is a dispute, or at least, a lack of clarity of fact as to this. This dispute of fact, however, is not material to this motion, since Plaintiff's complaint is aimed primarily at the exclusion of drugs from the preferred drug list and it is undisputed that many drugs are not on the list due to the failure of manufacturers to agree to Florida's 10% rebate. Indeed, as previously noted, at oral argument, Plaintiff conceded that there are no genuine disputes of material fact.

It is not disputed that the purpose of the prior authorization procedure is to encourage physicians to prescribe drugs on the preferred list, that is, drugs which are 10% less expensive to the Florida Medicaid program:

> The statute only calls for prior authorization of any drug that is not on the PDL [preferred drug list]. The authorization is guaranteed, but allows the State to make a prescribing physician aware of alternative prescription choices.

Doc. 20, affidavit of George Kitchens, ¶ 3.

> Under Florida's prior authorization program, each physician makes his or her own decision as [to] what to prescribe for each patient. If the prescribed drug is not on the PDL, then the pharmacist consultant employed by ACS Consultec advises the physician of alternatives. . . . If the physician, after hearing these alternatives, still prefers his or her specific choice, then that choice is approved. There is no penalty for the decision to prescribe a non-PDL drug. The State will abide by the wishes of the treating physician.

Id., ¶ 5. "Every drug available to Medicaid recipients prior to the passage of Chapter 2001-104, Laws of Florida, continues to be a covered drug under the PDL." *Id.*, ¶ 3.

It is recognized that Plaintiff's witnesses imply a different view as to the process, but the implication is not persuasive and does not create a dispute of fact. David Pickhardt states in his affidavit that "the prescription will not be covered under the plan or program without the administrator's approval." Doc. 8, attached affidavit of David Pickhardt. That is true, but the implication that the physician's choice will not be honored is untrue, as explained by Kitchens. On this record, the evidence is that the approval is automatic if the physician prefers the drug not on the preferred list.

Florida has hired an agent, ACS Consultec, to operate the prior authorization system. Doc. 20, affidavit of George Kitchens, ¶ 4. The "system" contemplates that ACS Consultec will provide an authorization within 24 hours of a request, and will dispense a 72 hour supply of the medication in emergency situations. *Id.* "The average communication time for a physician to obtain approval under the Florida PDL [preferred drug list] program is between 5 and 10 minutes." *Id.*

Plaintiff has shown that the market shares of a number of drugs of its members not on the preferred drug list have significantly fallen in recent months. Doc. 25, pp. 8-9. For example, the market share of Imitrex fell from 60% to 6%, the market share of Prilosec fell from 38% to 4%, and the market share of Allegra fell from 17% to 1%. *Id.*

The State list initially was adopted as a temporary preferred drug list. The new law directs that a Medicaid Pharmaceutical and Therapeutics Committee be appointed by the Governor. FLA. STAT. § 409.91195(1). "Until the Medicaid Pharmaceutical and Therapeutics Committee is appointed" by the Governor, "and a preferred drug list adopted by the agency," the existing "Florida Voluntary Preferred Drug List" shall be used as the interim list. Fla. Stat. § 409.01195(8). "Drugs not listed on the voluntary preferred drug list will require prior authorization by the agency or its contractor." *Id.* The temporary list went into effect on July 1, 2001, and will be phased out in stages as the permanent list is established. The temporary list has about 821 drugs from the federal list, or only about 44.9% of the federal list. Doc. 8, pp. 15-16. As noted above, about 1,006 drugs are subject to prior authorization.

The temporary list was adopted in June, 2001, by the existing Medicaid Pharmaceutical and Therapeutics Committee, which had appointees by not only the Governor, but by the presiding officers of the Florida House of Representa-

tives and the Senate. FLA. STAT. § 409.91195(1) (2000) (prior to amendment). However, a properly constituted Pharmaceutical and Therapeutics Committee, appointed by the Governor, met on August 25, 2001. That Committee approved, ratified, and adopted the interim preferred drug list. Doc. 20, affidavit of Ronald Salem, Pharm. D., ¶¶ 1-4.

III. Legal analysis

Defendants have not challenged Plaintiff's standing to bring this action, and there does not seem to be a standing problem which must be raised *sua sponte*. *See Florida Ass'n of Rehab. Facilities, Inc. v. State of Florida, Dept. of Health and Rehabilitative Serv.*, 225 F.3d 1208, 1216 n. 5 (11th Cir. 2000); *Pirolo v. City of Clearwater*, 711 F.2d 1006 (11th Cir. 1983); *Pharmaceutical Research and Mfrs. Of America v. Concannon*, 249 F.3d 66, 72-74 (1st Cir. 2001), *pet. for cert. filed*, 70 U.S.L.W. 3092 (July 31,2001).

A preliminary injunction will not issue unless the Plaintiff satisfies the four prerequisites for a preliminary injunction:

1. A substantial likelihood that plaintiff will prevail on the merits,
2. A substantial threat that the plaintiff will suffer irreparable injury if the injunction is not granted,
3. The threatened injury to plaintiff outweighs the threatened harm the injunction may do to defendant,
4. And the granting of the preliminary injunction will not disserve the public interest.

Canal Authority of Florida v. Callaway, 489 F.2d 567 (5th Cir. 1974). "The purpose of a preliminary injunction is always to prevent irreparable injury so as to preserve the court's ability to render a meaningful decision on the merits. It often happens that this purpose is furthered by preserva-

tion of the status quo, but not always. If the currently existing status quo itself is causing one of the parties irreparable injury, it is necessary to alter the situation so as to prevent the injury, either by returning to the last uncontested status quo between the parties, [citation omitted] or by allowing the parties to take proposed action that the court finds will minimize the irreparable injury." 489 F.2d at 576.

Likelihood of success on the merits should be addressed first, and that factor is dispositive here. Plaintiff contends that the new Florida law conflicts with Section 1927 of the Social Security Act, 42 U.S.C. § 1396r-8 and thus violates the Supremacy Clause. Plaintiff argues Florida's "preferred drug list" is actually a "formulary," and that the only drugs which a state may exclude from a "formulary" are those lacking a significant therapeutic value. Plaintiff argues that the Florida amendments conflict with the federal statute because these amendments allow drugs as to which the manufacturer has not agreed to the additional 10% rebate to be excluded from the list.[2]

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[2] Plaintiff had also argued that federal law authorizes a state to enter into a rebate agreement with a drug manufacturer only if the Secretary of the United States Department of Health and Human Services has authorized the state to do so. As noted above, the Secretary has now approved Florida's preferred drug list and program, effective July 1, 2001. Plaintiff conceded at oral argument that this basis for a preliminary injunction is now moot and it has been withdrawn. Plaintiff's third contention, that the Florida preferred drug list was adopted by an improperly constituted committee, is also moot, and Plaintiff so concedes. Doc. 25, p. 6, n. 7. As will be explained, a new committee, appointed by the Governor, has adopted and ratified Florida's drug list. Plaintiff withdrew this claim at oral argument.

"State action may be foreclosed by express language in a congressional enactment, *see, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992), by implication from the depth and breadth of a congressional scheme that occupies the legislative field, *see, e.g., Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U.S. 141, 153, 102 S. Ct. 3014, 73 L. Ed. 2d 664 (1982), or by implication because of a conflict with a congressional enactment, *see, e.g., Geier v. American Honda Motor Co.*, 529 U.S. 861, 869-874, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000)." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 121 S. Ct. 2404, 2414, 150 L. Ed. 2d 532 (2001).

Plaintiff does not argue express preemption. Nor does Plaintiff argue preemption by implication because the federal law occupies the field.[3] Plaintiff's claims rest upon the third type, conflict with federal law.

> "Such a conflict arises when 'compliance with both federal and state regulations is a

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[3] We can infer an "intent to occupy a given field to the exclusion of

> state law . . . where the pervasiveness of the federal regulation precludes supplementation by the States" or "where the federal interest in the field is sufficiently dominant. . . ." *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 300, 108 S. Ct. 1145, 1150, 99 L. Ed. 2d 316 (1988). We can also infer an intent to preempt where "'the object sought to be obtained by the federal law and the character of the obligations imposed by it'" reveal a purpose to preclude the enforcement of the state laws on the same subject. *Id.* (citation omitted).

Dietrich v. Key Bank, N.A., 72 F.3d at 1514.

> physical impossibility,' . . . or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. . . ." *Hillsborough County, Fla. v. Auto. Med.*, 471 U.S. 707, 713, 105 S. Ct. 2371, 2375, 85 L. Ed. 2d 714 (1985) (citations omitted).

Dietrich v. Key Bank, N.A., 72 F.3d 1509, 1513-1514 (11th Cir. 1996).

Since the Medicaid program is a joint federal and state effort, funded almost equally by both parties, it is expected that States may be afforded some latitude in the way in which they provide Medicaid to beneficiaries within their States:

> No state is obligated to participate in the Medicaid program. If a state opts to participate in the Medicaid program, however, it must do so in a manner that complies with federal statutory and regulatory requirements. *See* § 42 U.S.C. 1396n. Within the general framework of federal law, states that choose to participate in the Medicaid program (thus qualifying for federal financial aid covering the medical assistance costs of eligible individuals) are granted broad latitude in defining the scope of covered services as well as many other key characteristics of their programs.

Florida Ass'n of Rehab. Facilities, Inc., 225 F.3d at 1211.

> [F]ederal preemption of a state law is "strong medicine," and is "not casually to be dispensed." . . . This is especially true when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federal-

> ism": "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one."

Concannon, 249 F.3d at 75 (citations omitted).

Concannon is the only similar case to provide some guidance to the court. In *Concannon*, the State of Maine had established a program to lower drug costs to persons *not* covered by Medicaid. The statute allowed State officials to negotiate rebate agreements with drug manufacturers with the goal of obtaining a rebate in the same amount as the federal Medicaid rebate, 15.1%. 249 F.3d at 71. The rebate was then to be used to lower drug costs to persons not covered by Medicaid who elected to participate in the program. To encourage these rebate agreements, the drugs of manufacturers who refused to enter into such rebate agreements were subject to "prior authorization" under the Maine Medicaid program. *Id.* at 72. The court held that, as a facial challenge, the Maine program was not preempted by the federal Medicaid law. *Id.* at 78-79.

Plaintiff contends that the Florida drug "list" is a "formulary" as that word is used in 42 U.S.C. § 1396r-8(d)(4). Plaintiff argues that the Florida Statutes reflect an intent to create a drug formulary as intended by § 1396r-8(d)(4) because the amended statutes use the word "formulary." The Florida statutes use the phrases "preferred drug formulary" and "preferred drug list" interchangeably.[4] *E.g.*, FLA. STAT.

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[4] The title to Committee Substitute for Committee Substitute for Senate Bill 792, which became Chapter 2001-104, Laws of Florida, announces that the amendment to FLA. STAT. (continued...)

§ 409.91195(1), (4), (5), (6), (7), (8), (9), (11). Sometimes the first phrase is used (subsections (1), (5), and (6)), sometimes the second is used (subsections (7) and (8)), and sometimes both are used interchangeably in the same subsection (subsections (4) and (9)). Thus, while it would appear that the law intends a "preferred drug list" to be a "formulary," it would appear equally true that the Florida Statutes intend any "formulary" to be a "preferred drug list." Since the words are used so interchangeably, little can be inferred from the choice of words. Defendants, who are charged with implementing this Florida program, have interpreted the statute in the manner in which they have implemented it, and their interpretation is entitled to some deference.

Plaintiff argues that the Florida "list" is a "formulary" as intended by federal law because FLA. STAT. § 409.912(37)(a)(7) authorizes the agency to establish a "preferred drug formulary in accordance with 42 U.S.C. § 1396r-8." The problem with this argument is how the Florida Statute intends the phrase "preferred drug formulary" to be read. As indicated above, Florida law interchangeably uses the phrase "preferred drug formulary" to mean a "preferred drug list." Further, the reference is to section 1396r-8 generally, and not specifically to subsection (d)(4), in which the federal drug formulary is described. It is true that it is only in subsection (d)(4) that the federal law makes any reference to a "formulary," but since Florida law equates a "formulary" with a "preferred drug list," one cannot be sure that the Florida law is aimed only at the concept of a "drug formulary" as intended by subsection (d)(4).

All of this, however, does not lead to the light. Instead, it is more profitable to observe that 42 U.S.C. § 1396r-8(d) (in

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§ 409.91195 will require the establishment of a "preferred drug formulary." Doc. 8, attachment A.

which, obviously, (d)(4) is found) is entitled "Limitations on coverage of drugs." Subsection (d)(1)(A) states in part that "A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." *Moreover*, 42 U.S.C. § 1396r-8(d)(4) states: "A prior authorization program established by a State under paragraph (5) is *not a formulary subject to the requirements of this paragraph*." (Emphasis added.) Subparagraph (5) authorizes a State to create a "prior authorization program" to determine "coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section [section (4), concerning the federal drug formulary]. . . ."

The Florida program operates only as a prior authorization program. All of the drugs for which there are manufacturers' rebate agreements with the federal government are included in Florida's program, either on the preferred list, or when requested by a physician. Requests are automatically granted. Indeed, strictly speaking, the Florida program is not even an "authorization" program. It is only a program by which the State informs physicians of preferred, less expensive drugs. After this advice is given, the physician is permitted to prescribe drugs covered under the federal formulary but not on the Florida preferred drug list, if the physician prefers.

Thus, the Florida program does not invoke the authority of section 1396r-8(d)(4)(C) to exclude any drug from the federal drug formulary (that is, drugs without significant therapeutic advantage). The Committee created by the Florida Statute has simply adopted the federal drug formulary, and then added a prior authorization component.

That drugs, not on the preferred list and subject to prior authorization, have lost market share, is irrelevant here. The federal law does not purport to guarantee a market share. It

only requires that a State Medicaid program make available all of the drugs on the federal drug formulary.

That the process is cumbersome for physicians, or may deter them from prescribing drugs not on the State's preferred list, is of no moment to this Supremacy law claim, either. The evidence is that it takes only five or ten minutes for a physician to make the contact and obtain automatic approval. Federal law does not proscribe State programs which add steps to the process in the furtherance of legitimate State interests, particularly where the steps (prior authorization) are expressly permitted by federal law.

Nor, as a general matter, is the purpose of the prior authorization program antithetical to the Medicaid program. The purpose for which prior authorization is required is related to the goals of the Medicaid program, to provide drugs to Medicaid beneficiaries at the lowest cost possible.[5]

Plaintiff had argued that the Florida law establishes a Medicaid Pharmaceutical and Therapeutics Committee to be "comprised as specified in 42 U.S.C. § 1396r-8." Fla. Stat. § 409.91195(1). The law further provides that this Committee exists "for the purpose of developing a preferred drug formulary pursuant to 42 U.S.C. § 1396r-8." *Id.*, preamble. Upon recommendation of this Committee, the agency is to adopt a "preferred drug list." *Id.*, subsection (4). Plaintiff argues that the Florida law would not have insisted that this

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[5] In *Concannon*, the court said that it was "not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization, as long as the 24-hour response and the 72-hour drug-supply requirements, 42 U.S.C. § 1396r-8(d)(5), are satisfied." 249 F.3d at 76. Here, unlike in that case, there is a clear Florida Medicaid purpose served by the prior authorization program.

Committee be comprised as required by federal law if it did not intend the Committee to create a "formulary" as intended by § 1396r-8(d)(4). As noted above, one of the three requirements of federal law for the adoption of a state "formulary" under subsection (d)(4) is that it be developed by a committee of specified types of persons appointed by the Governor. 42 U.S.C. § 1396r-8(d)(4)(A). But the Committee has adopted the federal drug formulary in toto. It has not excluded any drug. If in the future it chooses to exclude a drug without significant therapeutic value as authorized by 42 U.S.C. § 1396r-8(d)(4)(C), it may do so because it is properly comprised. Further, there is nothing in the federal law that prohibits a Committee comprised in this way to have other functions, here, to adopt a preferred drug list with a prior authorization component.

Plaintiff argues that the federal statute provides that if a State *excludes* a drug for lack of significant therapeutic value, it must still make the drug available pursuant to the prior authorization program. Plaintiff argues from this that a prior authorization program is permitted for only this purpose, and not for the purpose adopted by Florida. But Plaintiff has pointed to nothing in the federal law which prohibits Florida from creating a prior authorization program for another purpose. Indeed, section (d)(4) takes pains to state that a prior authorization program is not a drug formulary as defined in section (d)(4), implying that a prior authorization program may be adopted to serve State purposes, purposes which may be different from federal purposes.

Nor has Plaintiff pointed to any portion of the federal law which forbids a State from seeking additional rebates from drug manufacturers. In the absence of a specific federal statutory provision, a State should be free, as any buyer in the market place, to try to obtain the best prices it can.

Finally, it is noted that since the federal statute commits the regulation of the Medicaid program to the Secretary, and

specifically authorizes the Secretary to permit States to enter into rebate agreements with drug manufacturers, it would appear that the Secretary's interpretation of the interaction of the federal Medicaid statute with Florida's law is entitled to at least some deference. *United States v. Mead Corp.*, 533 U.S. 218, 121 S. Ct. 2164, 2171-2172, 150 L. Ed. 2d 292 (2001). It would appear that the Secretary has considered these same issues and has reached the conclusion that the Florida law does not conflict with the federal law.

In summary, Plaintiff has not shown that "compliance with both federal and state regulations is a physical impossibility," or that the Florida law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" *Dietrich v. Key Bank, N.A.*, 72 F.3d at 1513-1514. Since Plaintiff has not shown a substantial likelihood of success, the motion for a preliminary injunction should be denied.

For these reasons, it is RECOMMENDED that Plaintiff's motion for a preliminary injunction, doc. 7, be DENIED.

IN CHAMBERS at Tallahassee, Florida, this 20th day of September, 2001.

WILLIAM C. SHERRILL, JR.

UNITED STATES MAGISTRATE JUDGE

NOTICE TO THE PARTIES

A party may file specific, written objections to the proposed findings and recommendations within 15 days after being served with a copy of this report and recommendation. A party may respond to another party's objections within 10 days after being served with a copy thereof. Failure to file specific objections limits the scope of review of proposed factual findings and recommendations.

SOCIAL SECURITY ACT § 1927
42 U.S.C. § 1396r-8 (in pertinent part)

§ 1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). . . .

. . . .

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) of this section or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

. . . .

(3) Manufacturer provision of price information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1) of this section) and, (for single source drugs and innovator multiple

source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this section) for covered outpatient drugs for the rebate period under the agreement, and

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs.

. . . .

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for

the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and

(V) after December 31, 1995, is 15.1 percent.

. . . .

(C) Best price defined

For purposes of this section—

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of Title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section;

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program; and

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.

(ii) Special rules

The term "best price"—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for

the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

. . . .

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section

or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or

clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient

prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

. . . .

(k) Definitions

In this section—

(1) Average manufacturer price

The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

(2) Covered outpatient drug

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 (21 U.S.C. 355) or 507 of the Federal Food, Drug, and Cosmetic Act

or which is approved under section 505(j) of such Act (21 U.S.C. 355(j));

(ii) (I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (p))) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act (21 U.S.C. 331, 332(a), 334(a)) to enforce section 502(f) or 505(a) of such Act (21 U.S.C. 352(f), 355(a)); or

(iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (e)) on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed,

recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

(4) Nonprescription drugs

If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer

The term "manufacturer" means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or inde-

pendently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

. . . .

(8) Rebate period

The term "rebate period" means, with respect to an agreement under subsection (a) of this section, a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency

The term "State agency" means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

FLA. STAT. § 409.91195 (in pertinent part)

409.91195 Medicaid Pharmaceutical and Therapeutics Committee

There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration for the purpose of developing a preferred drug formulary pursuant to 42 U.S.C. s. 1396r-8.

(1) The Medicaid Pharmaceutical and Therapeutics Committee shall be comprised as specified in 42 U.S.C. s. 1396r-8 and consist of 11 members appointed by the Governor. Four members shall be physicians, licensed under chapter 458; one member licensed under chapter 459; five members shall be pharmacists licensed under chapter 465; and one member shall be a consumer representative. The members shall be appointed to serve for terms of 2 years from the date of their appointment. Members may be appointed to more than one term. The Agency for Health Care Administration shall serve as staff for the committee and assist them with all ministerial duties. The Governor shall ensure that at least some of the members of the Medicaid Pharmaceutical and Therapeutics Committee represent Medicaid participating physicians and pharmacies serving all segments and diversity of the Medicaid population, and have experience in either developing or practicing under a preferred drug formulary. At least one of the members shall represent the interests of pharmaceutical manufacturers.

(2) Committee members shall select a chairperson and a vice chairperson each year from the committee membership.

(3) The committee shall meet at least quarterly and may meet at other times at the discretion of the chairperson and members. The committee shall comply with rules adopted by the agency, including notice of any meeting of the committee pursuant to the requirements of the Administrative Procedure Act.

(4) Upon recommendation of the Medicaid Pharmaceutical and Therapeutics Committee, the agency shall adopt a preferred drug list. To the extent feasible, the committee shall review all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the formulary, such that the formulary provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

(5) Except for mental health-related drugs, antiretroviral drugs, and drugs for nursing home residents and other institutional residents, reimbursement of drugs not included in the formulary is subject to prior authorization.

(6) The Agency for Health Care Administration shall publish and disseminate the preferred drug formulary to all Medicaid providers in the state.

(7) The committee shall ensure that interested parties, including pharmaceutical manufacturers agreeing to provide a supplemental rebate as outlined in this chapter, have an opportunity to present public testimony to the committee with information or evidence supporting inclusion of a product on the preferred drug list. Such public testimony shall occur prior to any recommendations made by the committee for inclusion or exclusion from the preferred drug list. Upon timely notice, the agency shall ensure that any drug that has been approved or had any of its particular uses approved by the United States Food and Drug Administration under a priority review classification will be reviewed by the Medicaid Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting. To the extent possible, upon notice by a manufacturer the agency shall also schedule a product review for any new product at the next regularly scheduled Medicaid Pharmaceutical and Therapeutics Committee.

(8) Until the Medicaid Pharmaceutical and Therapeutics Committee is appointed and a preferred drug list adopted by the agency, the agency shall use the existing voluntary preferred drug list adopted pursuant to s. 72, chapter 2000-367, Laws of Florida. Drugs not listed on the voluntary preferred drug list will require prior authorization by the agency or its contractor.

(9) The Medicaid Pharmaceutical and Therapeutics Committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and cost-effectiveness of a product. When the preferred drug formulary is adopted by the agency, if a product on the formulary is one of the first four brand-name drugs used by a recipient in a month the drug shall not require prior authorization.

(10) The Medicaid Pharmaceutical and Therapeutics Committee may also make recommendations to the agency regarding the prior authorization of any prescribed drug covered by Medicaid.

(11) Medicaid recipients may appeal agency preferred drug formulary decisions using the Medicaid fair hearing process administered by the Department of Children and Family Services.

FLA. STAT. § 409.91195 (in pertinent part)

409.912. Cost-effective purchasing of health care

The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency may establish prior authorization requirements for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization.

> (1) The agency may enter into agreements with appropriate agents of other state agencies or of any agency of the Federal Government and accept such duties in respect to social welfare or public aid as may be necessary to implement the provisions of Title XIX of the Social Security Act[1] and ss. 409.901-409.920.
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[1] 42 U.S.C.A. § 1396 et seq.

(9) The agency, after notifying the Legislature, may apply for waivers of applicable federal laws and regulations as necessary to implement more appropriate systems of health care for Medicaid recipients and reduce the cost of the Medicaid program to the state and federal governments and shall implement such programs, after legislative approval, within a reasonable period of time after federal approval. These programs must be designed primarily to reduce the need for inpatient care, custodial care and other long-term or institutional care, and other high-cost services.

. . . .

(10) The agency shall establish a postpayment utilization control program designed to identify recipients who may inappropriately overuse or underuse Medicaid services and shall provide methods to correct such misuse.

(11) The agency shall develop and provide coordinated systems of care for Medicaid recipients and may contract with public or private entities to develop and administer such systems of care among public and private health care providers in a given geographic area.

(12) The agency shall operate or contract for the operation of utilization management and incentive systems designed to encourage cost-effective use services.

. . . .

(14)(a) The agency shall identify health care utilization and price patterns within the Medicaid program which are not cost-effective or medically appropriate and assess the effectiveness of new or alternate methods of providing and monitoring service, and

may implement such methods as it considers appropriate. Such methods may include disease management initiatives, an integrated and systematic approach for managing the health care needs of recipients who are at risk of or diagnosed with a specific disease by using best practices, prevention strategies, clinical-practice improvement, clinical interventions and protocols, outcomes research, information technology, and other tools and resources to reduce overall costs and improve measurable outcomes.

(b) The responsibility of the agency under this subsection shall include the development of capabilities to identify actual and optimal practice patterns; patient and provider educational initiatives; methods for determining patient compliance with prescribed treatments; fraud, waste, and abuse prevention and detection programs; and beneficiary case management programs.

1. The practice pattern identification program shall evaluate practitioner prescribing patterns based on national and regional practice guidelines, comparing practitioners to their peer groups. The agency and its Drug Utilization Review Board shall consult with a panel of practicing health care professionals consisting of the following: the Speaker of the House of Representatives and the President of the Senate shall each appoint three physicians licensed under chapter 458 or chapter 459; and the Governor shall appoint two pharmacists licensed under chapter 465 and one dentist licensed under chapter 466 who is an oral surgeon. Terms of the panel members shall expire at the discretion of the appointing official. The panel shall begin its work by August 1, 1999, regardless of the number of

appointments made by that date. The advisory panel shall be responsible for evaluating treatment guidelines and recommending ways to incorporate their use in the practice pattern identification program. Practitioners who are prescribing inappropriately or inefficiently, as determined by the agency, may have their prescribing of certain drugs subject to prior authorization.

2. The agency shall also develop educational interventions designed to promote the proper use of medications by providers and beneficiaries.

3. The agency shall implement a pharmacy fraud, waste, and abuse initiative that may include a surety bond or letter of credit requirement for participating pharmacies, enhanced provider auditing practices, the use of additional fraud and abuse software, recipient management programs for beneficiaries inappropriately using their benefits, and other steps that will eliminate provider and recipient fraud, waste, and abuse. The initiative shall address enforcement efforts to reduce the number and use of counterfeit prescriptions.

4. By September 30, 2002, the agency shall contract with an entity in the state to implement a wireless handheld clinical pharmacology drug information database for practitioners. The initiative shall be designed to enhance the agency's efforts to reduce fraud, abuse, and errors in the prescription drug benefit program and to otherwise further the intent of this paragraph.

5. The agency may apply for any federal waivers needed to implement this paragraph.

. . . .

(38)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. Medicaid prescribed-drug coverage for brand-name drugs for adult Medicaid recipients is limited to the dispensing of four brand-name drugs per month per recipient. Children are exempt from this restriction. Antiretroviral agents are excluded from this limitation. No requirements for prior authorization or other restrictions on medications used to treat mental illnesses such as schizophrenia, severe depression, or bipolar disorder may be imposed on Medicaid recipients. Medications that will be available without restriction for persons with mental illnesses include atypical antipsychotic medications, conventional antipsychotic medications, selective serotonin reuptake inhibitors, and other medications used for the treatment of serious mental illnesses. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply. The agency shall continue to provide unlimited generic drugs, contraceptive drugs and items, and diabetic supplies. Although a drug may be included on the preferred drug formulary, it would not be exempt from the four-brand limit. The agency may authorize exceptions to the brand-name-drug restriction based upon the treatment needs of the patients, only when such exceptions are based on prior consultation provided by the agency or an agency contractor, but

the agency must establish procedures to ensure that:

a. There will be a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation;

b. A 72-hour supply of the drug prescribed will be provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.; and

c. Except for the exception for nursing home residents and other institutionalized adults and except for drugs on the restricted formulary for which prior authorization may be sought by an institutional or community pharmacy, prior authorization for an exception to the brand-name-drug restriction is sought by the prescriber and not by the pharmacy. When prior authorization is granted for a patient in an institutional setting beyond the brand-name-drug restriction, such approval is authorized for 12 months and monthly prior authorization is not required for that patient.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the average wholesale price less 13.25 percent.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medi-

cal-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease-management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-participating providers.

5. The agency shall develop and implement a program that requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by Medicaid-participating prescribers or prescribers who write prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug formulary in accordance with 42 U.S.C. s. 1396r-8, and, pursuant to the establishment of such formulary, it is authorized to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 10 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 25 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug formulary. However, a pharmaceutical manufacturer is not guaranteed placement on the formulary by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the

Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency is authorized to contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" may include, at the agency's discretion, cash rebates and other program benefits that offset a Medicaid expenditure. Such other program benefits may include, but are not limited to, disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program in the same year the rebate reduction is included in the General Appropriations Act. The agency is authorized to seek any federal waivers to implement this initiative.

8. The agency shall establish an advisory committee for the purposes of studying the feasibility of using a restricted drug formulary for nursing home residents and other institutionalized adults. The committee shall be comprised of seven members appointed by the Secretary of Health Care Administration. The committee members shall include two physicians licensed under chapter 458 or chapter 459; three pharmacists licensed under chapter 465 and appointed from a list of recommendations provided by the Florida Long-Term Care Pharmacy Alliance; and two pharmacists licensed under chapter 465.

9. The Agency for Health Care Administration shall expand home delivery of pharmacy products. To assist Medicaid patients in securing their

prescriptions and reduce program costs, the agency shall expand its current mail-order-pharmacy diabetes-supply program to include all generic and brand-name drugs used by Medicaid patients with diabetes. Medicaid recipients in the current program may obtain nondiabetes drugs on a voluntary basis. This initiative is limited to the geographic area covered by the current contract. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

(b) The agency shall implement this subsection to the extent that funds are appropriated to administer the Medicaid prescribed-drug spending-control program. The agency may contract all or any part of this program to private organizations.

(c) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed-drug expenditures.

(39) Notwithstanding the provisions of chapter 287, the agency may, at its discretion, renew a contract or contracts for fiscal intermediary services one or more times for such periods as the agency may decide; however, all such renewals may not combine to exceed a total period longer than the term of the original contract.

(40) The agency shall provide for the development of a demonstration project by establishment in Miami-Dade County of a long-term-care facility licensed pursuant to chapter 395 to improve access to health care for a predominantly minority, medically

underserved, and medically complex population and to evaluate alternatives to nursing home care and general acute care for such population. Such project is to be located in a health care condominium and colocated with licensed facilities providing a continuum of care. The establishment of this project is not subject to the provisions of s. 408.036 or s. 408.039. The agency shall report its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2003.

[Attach. 2 to Decl. of Russel A. Bantham, *PhRMA v. Medows*, No. 4:01cv356-WS (N.D. Fla.) (filed Aug. 7, 2001).]

AGENCY FOR HEALTH CARE ADMINISTRATION

Pharmaceutical Manufacturers Formulary
& Supplemental Rebate Briefing

May 31, 2001

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[p. 67] MR. KITCHENS: Again, I think that's a conversation where, when the physician calls in, he's going to be prepared to state his position as to why he believes that's medically necessary.

[Attach. 3 to Decl. of Russel A. Bantham, *PhRMA v. Medows*, No. 4:01cv356-WS (N.D. Fla.) (filed Aug. 7, 2001).]

STATE OF FLORIDA

PHARMACEUTICAL AND THERAPEUTICS COMMITTEE

Tuesday, June 26, 2001

9:20 a.m. - 10:51 p.m.

* * * *

[p. 44] MR. KITCHENS:

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I think also in this prior auth process that there's a discussion that even that there may be some difference of opinion that a prior auth is approved and there may be some clarification paperwork sent to the physician and so you got prior auth 30 days and it opens window for further discussion.

So I would hope during that 30 days Consult Tech has not fallen through in not responding to calls. That would be a major issue for me, but there should be no holding back of therapy for patients based on both 72-hour supply and once you do talk to a pharmacy at ACS Consult Tech that you're given that 30-day window to provide more clinical information is necessary.

[Exh. E to Defendant's Contested Mot. to File Supp. Affidavit, *PhRMA v. Medows*, No. 4:01cv356-WS (N.D. Fla.) (filed Sept. 19, 2001).]

[State of Florida, AHCA logo]

September 14, 2001

Mr. Eugene A. Grasser
Associate Regional Administrator
Centers for Medicare and Medicaid Services
61 Forsyth Street SW, Suite 4T20
Atlanta, GA 30303-9909

Dear Mr. Grasser:

Thank you for your attention to our pending state plan amendment. Attached are revised pages for the two places this amendment will appear in our plans. Please replace these pages with the enclosed.

Thank you again for your help.

Sincerely,

Bob Sharpe
Deputy Secretary for Medicaid

* * * *

Preferred Drug List with Prior Authorization: In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. s1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list. The makeup and appointment authority for the Pharmaceutical and Therapeutic Committee is modified to comply with 42 U.S.C. s1396r-8.